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REPORT
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HEALTH RESEARCH EXTENSION ACT OF 1985

JULY 15, 1985.—Ordered to be printed

Mr. HATCH, from the Committee on Labor and Human Resources, submitted the following

REPORT

[To accompany S. 1309]

The Committee on Labor and Human Resources, to which was referred the bill (S. 1309) to amend the Public Health Service Act to revise and extend the authorities under that Act relating to the National Institutes of Health and National Research Institutes, and for other purposes, having considered the same, reports favorably thereon without amendment and recommends that the bill do pass.

CONTENTS

	Page
I. Summary of the Bill	1
II. Background and Need for Legislation	4
III. History of S. 1309	6
IV. Hearings	7
V. Committee Views	7
VI. Text of S. 1309 as Reported	16
VII. Budget Estimate	79
VIII. Administration Views	81
IX. Regulatory Impact Statement	82
X. Section by Section Analysis	82
XI. Changes in Existing Law	89

I. SUMMARY OF THE BILL

S. 1309 amends the Public Health Service Act (PHSA) and makes additional provisions as follows:

(1) Provides specific statutory authority for the National Institutes of Health (NIH) as an agency of the Public Health Service.

(a) Establishes in statute twelve national research institutes as agencies of the NIH, including two institutes (the National Insti-

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tute of Diabetes and Digestive and Kidney Diseases; and the National Institute of Arthritis and Musculoskeletal and Skin Diseases) whose functions were formerly combined under one institute.

(b) Establishes in statute three non-research entities of NIH (the National Library of Medicine; the Division of Research Resources; and the John E. Fogarty Intenational Center for Advanced Study in the Health Sciences) as agencies of NIH.

(c) Grants authority to the Secretary of the Department of Health and Human Services (DHHS) to create, reorganize, or abolish research institutes after appropriate notification to Congress.

(2) Provides for the appointment and outlines the duties and authority of the Director of NIH.

(a) Requires the Director to assure that NIH intramural research is subject to peer review.

(b) Requires the Director to prepare a biennial report for submission to the President and to Congress.

(c) Establishes within the Office of the NIH Director the position of Associates Director for Prevention.

(3) Sets forth general provisions respecting the twelve national research institutes.

(a) Provides for the appointment (by the President) of the Director of the National Cancer Institute.

(b) Provides for the appointment (by the DHHS Secretary) of the Directors of all the other research institutes.

(c) Provides for the appointment of an advisory council for each of the national research institutes, and prescribes their special functions and duties.

(d) Extends the authorization of appropriations for the programs of the National Cancer Institute and the National Heart, Long, and Blood Institute through FY88.

(4) Sets forth specific provisions respecting the twelve national research institutes.

(a) Describes the purpose of each of the institutes, outlines the responsibilities and functions of the various directors, boards, committees, panels, research and demonstration centers, information clearinghouses, and other programs associated with the institutes.

(b) Establishes positions for Associate Directors for Prevention within the National Cancer Institute, the National Heart, Lung, and Blood Institute, and the National Institute on Child Health and Human Development.

(c) Provides for the development or expansion of centers for research and training in diabetes, digestive diseases, and kidney and urologic diseases.

(d) Authorizes the National Institute on Aging to support centers of basic and clinical research into various aspects of Alzheimer's disease.

(e) Authorizes the National Institute of Child Health and Human Development to support research regarding the cause, prevention and treatment of mental retardation.

(f) Authorizes the National Institute of Neurological and Communicative Disorders and Stroke to support research on spinal cord regeneration, and on bioengineering for purposes of overcoming paralysis.

(5) Establishes in statute the National Library of Medicine.

(a) Outlines the specific duties and functions of the Library and its Board of Regents.

(b) Authorizes appropriations for the Medical Library Assistance Act programs through FY88.

(6) Sets forth provisions respecting the National Research Service Awards (NRSA) program for research and training in biomedical and behavioral research.

(a) Specifies application and award procedures, as well as payback requirements for NRSA recipients.

(b) Authorizes appropriations for NRSA grant payments through FY88.

(c) Requires the DHHS Secretary to conduct a study of the NRSA program and its requirements, including the effect of the payback requirement on the number of persons who engage in health research or training as a career.

(7) Provides for a Visiting Scientist Awards program to enable certain post-secondary educational institutions (those with a significant enrollment of disadvantaged students) to benefit from the special talents of scientists from other institutions.

(8) Requires the DHHS Secretary to arrange for a study every five years of the Nation's overall biomedical and behavioral research personnel needs, and to assess current training programs available through the national research institutes and the Alcohol, Drug Abuse, and Mental Health Administration (ADAMHA).

(9) Requires the establishment of Institutional Review Boards (IRBs) by each entity applying for Federal funds to conduct biomedical or behavioral research involving human subjects.

(a) Provides for a DHHS program to give ethical guidance to research institutions.

(b) Provides for the establishment of a process for NIH to respond to reports of violations of the rights of human research subjects.

(10) Directs the DHHS Secretary to require, by regulation, an appropriate system of technical and scientific peer review of all extramural grants, contracts and cooperative agreements administered through the NIH. Also requires the NIH Director to establish procedures for periodic technical and scientific peer review of intramural research at NIH.

(11) Provides for the promulgation of DHHS regulations to require each entity receiving Federal funds for the conduct or support of biomedical or behavioral research to establish an administrative process to review reports of scientific fraud in such research.

(12) Provides for expedited grant review procedures in case of public health emergencies, and authorizes administrative supplemental increases in relevant existing grants and contracts.

(13) Sets forth provisions respecting the care and treatment of animals in research.

(a) Provides for the establishment of NIH guidelines for the proper care and treatment of animals used in biomedical and behavioral research supported by funds under this Act.

(b) Requires that animal care committees be established at each entity that conducts such research involving animals.

(c) Requires the NIH Director (with the assistance of an interagency coordinating committee) to establish a plan for research into alternatives to the use of animals in such research.

(14) Sets forth provisions concerning federally-supported research on human fetuses.

(a) Prohibits the conduct or support of research experimentation involving the use of any living fetus unless certain criteria are met.

(b) Requires that the risk standard published in the Code of Federal Regulations be the same for fetuses which are intended to be aborted, and fetuses which are intended to be carried to term.

(c) Directs the Biomedical Ethics Advisory Committee (created by this legislation) to conduct a study of the nature, advisability, and biomedical and ethical implications of exercising any waiver of this risk standard. Prohibits the Secretary from granting any such waiver for 36 months.

(15) Reaffirms that Section 301 of the Public Health Service Act represents the general legislative authority for NIH programs, and that the Secretary's authority under Section 301 is not limited by the provisions of Title IV.

(16) Establishes three interagency committees on specific research-related problems which are to report on their activities within 18 months and then terminate:

(a) Lupus Erythematosus Coordinating Committee.

(b) Interagency Committee on Spinal Cord Injury.

(c) Interagency Committee on Learning Disabilities.

(17) Requires the Secretary to conduct a special study on the adequacy and availability of health care personnel to meet the needs of elderly Americans through the year 2020.

(18) Requires a review of the disease research programs of the National Institute of Diabetes and Digestive and Kidney Diseases.

(19) Establishes in the legislative branch of Government a permanent Biomedical Ethics Advisory Board and a Biomedical Ethics Advisory Committee to study and report to the Congress on the ethical issues arising in biology and medicine. Authorizes appropriations for the Board and Committee through FY88.

(20) Sets October 1, 1985 as the effective date of this Act.

II. Background and Need for Legislation

The Health Research Extension Act of 1985 revises Title IV of the Public Health Service Act relating to the statutory authority of the National Institutes of Health (NIH) and its programs. Renewed authorizations are provided for several major programs whose authority had all expired by the end of fiscal year 1983. Additional provisions of importance to the Nation's biomedical research effort are also contained in the bill.

The National Institutes of Health is the principal medical research arm of the Federal Government. As one of the agencies of the Public Health Service, a component of the U.S. Department of Health and Human Services (DHHS), NIH has the mission of improving the health of the nation by increasing our understanding of the processes underlying human health and by acquiring new knowledge to help prevent, detect, diagnose, and treat disease. The National Institutes of Health began as a one-room laboratory of hy-

giene established in 1887, and in the years since has grown to a complex of eleven research Institutes and associated support divisions and activities.

NIH and its programs derive their statutory authority from Titles III and IV of the Public Health Service Act (PHSA). In the current law, there is no consistent, comprehensive authority for NIH as an agency or for the individual institutes that make it up. The major portion of the Health Research Extension Act of 1985 is a revision of Title IV of the PHSA, designed to clarify the purpose and roles of the institutes without altering or diminishing the authority under which the Federal Government sponsors health-related research. In particular, the bill reaffirms that Section 301 of the PHSA represents the general legislative authority for NIH programs, and that the DHHS Secretary's authority to conduct research under Section 301 is not limited by the provisions of Title IV.

The bill extends for three years the authorization of appropriations for the two largest institutes, the National Cancer Institute and the National Heart, Lung, and Blood Institute. The authorization levels provide for moderate increases in the funding of new and competing grants, and for the maintenance of current services with some new initiatives possible. This legislation will continue to strengthen the excellent research programs of these institutes which have contributed significantly to our increased understanding of the major killing diseases. Three-year authorizations are also made for the Medical Library Assistance Act programs of the National Library of Medicine and for the National Research Service Awards (training grant) program. These two assistance programs are both critical for maintaining the flow of trained biomedical researchers and information specialists.

An important feature of the bill is the creation of a new National Institute of Arthritis and Musculoskeletal and Skin Diseases. In its more than 100 forms, arthritis and related musculoskeletal diseases afflict some 49 million Americans, or 20 percent of the population. Not only the elderly are affected but also adults in the prime of life and an estimated 250,000 children. In the past three year, both the Senate and the House have voted several times to approve legislation creating a new Arthritis Institute. The creation of the new institute will allow us to focus a national effort on research for the prevention, diagnosis, treatment, and eventual cure of arthritis and related debilitating diseases.

Several additional research-related issues are addressed in the bill. The legislation includes provisions defining the circumstances under which research involving living human fetuses may be conducted, and provisions concerning the proper care, treatment, and use of animals in research. These provisions reflect the concerns of a broad spectrum of people and have been developed through lengthy and sensitive negotiations between representatives of differing viewpoints. Several time-limited studies or commissions are established to address concerns of great national interest—spinal cord injury, personnel for health needs of the elderly, learning disabilities, and lupus erythematosus. The commissions will terminate after completing their reports. The bill establishes one new permanent body, the Biomedical Ethics Board, in the legislative branch of

Government. This Board fills a critical need for continuing evaluation and objective analysis of the many biomedical research policy issues confronted by legislators. Two areas requiring examination that are specifically highlighted in the bill are the fetal research issue and the implications for human genetics of developments in genetic engineering.

S. 1309 is similar to NIH reauthorization legislation that passed the 98th Congress after a protracted course through both the Senate and House. Final form of the Health Research Extension Act of 1984 (S. 540) was worked out in conference committee and was overwhelmingly approved by both Houses of Congress. The President pocket vetoed the bill at the end of the session, citing objections to its new organizational entities and some of its new requirements for the management of research. The present bill omits the National Institute of Nursing that was proposed in S. 540, and incorporates several other minor modifications or deletions. All of the changes are intended to give flexibility and freedom to our research scientists and administrators, while maintaining appropriate accountability for public funds.

III. History of S. 1309

A bill, S. 1309, to amend the Public Health Service Act to revise and extend the authorities under the Act relating to the National Institutes of Health and National Research Institutes, and for other purposes was introduced by Senator Hatch on June 17, 1985, and was referred to the Committee on Labor and Human Resources.

On June 27, 1985, the bill was polled out of Committee. The Committee unanimously approved the bill and ordered that it be reported favorably to the Senate.

During the 98th Congress, the Committee considered and reported S. 773, the Biomedical Research, Training, and Medical Library Assistance Amendments of 1983 (S. Rept. 98-110, May 16, 1983). Holds were placed on the bill and it was not brought up for consideration by the Senate. A separate bill to establish a National Institute of Arthritis and Musculoskeletal and Skin Diseases (S. 540, introduced February 22, 1983 by Senator Goldwater) was discharged from the Committee by unanimous consent, was amended to create an Ethics Advisory Committee within the Office of Technology Assessment (OTA) and to give OTA authority to study bioethical issues, and was passed by the Senate on May 24, 1984. On June 5, 1984, the House passed S. 540, substituting the language of H.R. 2350, the Health Research Extenson Act of 1983, which has passed the House on November 17, 1983. On October 5, 1984, the Conference Report on S. 540 (H. Rept. 98-1155) was filed. On October 9, 1984, the Conference Report was approved by the House and Senate and S. 540 was reported to the President. S. 540 was pocket-vetoed by the President on October 30, 1984.

During the 97th Congress, the Committee considered and reported S. 2311, the Biomedical Research, Training, and Medical Library Assistance Amendments of 1982 (S. Rept. 97-461, May 28, 1982). Holds were placed on the bill and it was not brought up for consideration by the Senate. A separate bill to establish a National Insti-

tute of Arthritis and Musculoskeletal and Skin Disease (S. 1939, introduced by Senator Goldwater), was passed by the Senate on December 21, 1982. In the House, a unanimous consent request to consider the measure was rejected and the bill was not considered further.

IV. Hearings

No hearings were held during the 99th Congress on S. 1309, the Health Research Extension Act of 1985. The Committee did not believe additional hearings were necessary, because of thorough earlier hearings.

In the 98th Congress, the Committee held a public hearing on S. 773, the Biomedical Research, Training, and Medical Library Assistance Amendments of 1983, on March 17, 1983. Testimony was received from 11 witnesses, including the Assistant Secretary for Health of the Department of Health and Human Services, the Director of the National Institutes of Health and four of the Institute Directors, and representatives of research and professional organizations.

In the 97th Congress, the Committee held a public hearing on S. 2311, the Biomedical Research, Training, and Medical Library Assistance Amendments of 1982, on March 31, 1982. In addition, oversight hearings devoted to activities of the National Cancer Institute were held by the full Committee on June 2, 1981, and by the Subcommittee on Investigations on May 21, 1981, November 3, 1981, November 6, 1981, and March 5, 1982.

V. Committee Views

The NIH reauthorizing legislation has been considered during the past three Congresses. In the 97th Congress, the Senate bill, S. 2311, was favorably reported from Committee on May 28, 1982 (S. Rept. 97-461), and placed on the calendar for consideration by the Senate. However, holds were placed on the bill and it was not brought up for discussion or vote. In the 98th Congress, similar legislation, S. 773, was also favorably reported from Committee on April 13, 1983. The House succeeded in passing an NIH reauthorization bill H.R. 2350 on November 17, 1983, and requested conference with the Senate. The House-passed version changed existing law significantly by recodifying Title IV of the Public Health Service Act and specifying the duties of the eleven existing institutes at NIH. It also authorized establishment of two new institutes—a National Institute of Arthritis, Musculoskeletal and Skin Diseases, and a National Institute of Nursing—as well as several commissions to study specific diseases or health problems and make recommendations for research priorities. The Senate then passed a bill authorizing the National Institute of Arthritis, Musculoskeletal and Skin Diseases (S. 540) on May 24, 1984, and sent it to the House requesting a conference. In response, the House stripped the text of S. 540, substituted the text of H.R. 2350, and requested a conference. Conferees were appointed, and the conference was concluded, after significant changes were made in the House-passed bill, on October 5, 1984. The House and Senate approved the conference bill, and the bill was sent to the President for approval on

October 18, 1984. However, the bill was pocket vetoed by the President, and on October 30, 1984, a Memorandum of Disapproval was issued. Excerpts from that memorandum follow:

> I am withholding my approval of S. 540, the "Health Research Extension Act of 1984," which would extend and amend the biomedical research authorities of the National Institutes of Health (NIH).
>
> Creating unnecessary, expensive new organizational entitities;
>
> Mandating overly specific requirements for the management of research that place undue constraints on Executive branch authorities and functions;
>
> Going beyond the Administration's request to extend only expiring authorities by rewriting all the relevant statutes of the NIH;

Senators Hatch and Kennedy re-introduced NIH reauthorizing legislation in the 99th Congress on June 17, 1985. In response to the President's disapproval message, changes were made to reduce Congressional requirements considered to be unnecessary and overly directive. Senator Hatch's statement on the floor of the Senate when the bill was introduced responded to the President's concerns by stating:

> The bill I am introducing today provides, perhaps, the most critical ingredient in a successful research endeavor—stability. The veto message of S. 540 cited objections to a budget which exceeded that of the Administration. I am pleased to have been part of recent negotiations in the Senate related to the NIH budget. Several of my colleagues and I met with Mr. David Stockman, Director of the Office of Management and Budget, and coveyed strong Congressional support for our biomedical research effort. Mr. Stockman expressed support for increasing the NIH budget so that 6,000 new and competing grants can be funded annually for the next three years. My bill adopts this agreed-upon level, as well as providing funds sufficient to maintain current services. It is essential that we provide for economic stability of research effort. Inadequate funding is only part of the problem. I have heard repeatedly from representatives of the scientific community and academia that "mixed messages" from administrators at NIH, the Office of Management and Budget, and Congress result in considerable confusion and poor morale among research scientists. This has a particular negative impact upon talented young people who, while interested in becoming research scientists, are discouraged from pursuing such a career because of perceptions of inadequate funding. Historically, government support for research has been good. But when young people embarking on a research career hear repeatedly from their mentors that research grants are in jeopardy, they cannot be blamed for seeking a more predictable and stable environment in which to work. I believe this factor alone makes it critical that this legislation be enacted into law. We need to assure

a consensus for a stable level of federal support for basic biomedical science.

Over the past few years, there were a number of sensitive negotiations regarding research issues not related to funding. These included concerns expressed by a large number of our citizens, through focused interest groups, about animal welfare and fetal research. After investing a great deal of energy and time in considering disparate points of view, agreements were achieved. I believe they fairly represent the concerns of a broad spectrum of people, including very legitimate worries expressed by scientists. They should be enacted into law.

The last objection of the S. 540 veto message cited unnecessary congressional intrusion—"micromanagement." In truth, the legislation passed last year is relatively free of specific congressional direction. After listening to numerous proponents of disease targeted research, reviewing proposals for set-aside funding for particular projects, and considering multiple request for administrative changes, we distilled such concerns to a small number of congressional directives. In fact, in place of permanent changes, we authorized establishment of only time-limited studies or commissions to address concerns of great national interests—spinal cord injury, personnel for health needs of the elderly, learning disabilities, and lupus erythematosis. After completing reports to Congress, these commissions cease to exist. The legislation introduced today again includes these directives. I believe that both the public and our scientists stand to benefit from the information these reports will provide. I do not believe it is likely that additional legislative authorities will be needed to achieve recommendations the reports might make.

In order to respond to objections raised by the Administration to specific provisions in last year's conferenced bill, I have included several minor modifications or deletions. All of the changes are intended to give flexibility and freedom to our research scientists and administrators, while maintaining appropriate accountability for public funds.

The Committee believes that this reauthorizing legislation is essential and appropriate. In incorporates the recodification of Title IV of the Public Health Service Act, clarifying the research mission of each research institute at NIH, but it does not alter or diminish the general authority (Section 301) under which the Secretary of HHS conducts health-related research. It reemphasizes the importance of the National Cancer Act by maintaining the special authorities of the Director of the National Cancer Institute (NCI). It maintains the momentum of our battle against cardiovascular, lung, and blood diseases by authorizing a significant increase in appropriations for the National Heart, Lung, and Blood Institute and leaving unchanged this Institute's current legislative mandate.

The most significant change in the bill is the creation of the National Institute of Arthritis, and Musculoskeletal and Skin Diseases. Legislation to accomplish this has been passed by each house

of Congress separately, as part of an NIH reauthorizing bill, during the past two Congresses; however, it was not signed into law. The Committee reaffirms its support for establishing this new administrative unit at NIH. The new institute will provide for an expanded and more focused national research effort targeted to finding improved methods of preventing, treating, and, hopefully, curing arthritis.

Arthritis is actually more than 100 different disorders, which afflict some 49 million of our citizens and, along with skin disorders, collectively result in an extraordinary loss to our ecomony from lost productivity as well as from medical expense. We agree with the motto of the National Arthritis Foundation—"it's time we took arthritis seriously."—This new institute will provide a major increased focus on arthritis and musculoskeletal and skin diseases.

Concurrent with establishing this new institute, there will be created a National Institute of Diabetes and Digestive and Kidney Diseases. This will provide for ongoing and improved research efforts in these disease categories. At present, there is much promise held by research devoted to finding a cure for diabetes. Youngsters who develop diabetes early in life may, in fact, be suffering the consequences of an infectious disease which could be entirely preventable. Others, who have insulin-dependent diabetes, may eventually be cured if improved methods of pancreatic beta cell transplantation can be found. In short, there is justifiable optimism about finding a cure for diabetes; we may dare to begin hoping that diabetes may soon join the ranks of other diseases which have become part of medical history.

Perhaps the most controversial aspect of S. 540 was the mandate to establish a new National Institute of Nursing at NIH. This provision was added to H.R. 2350 as a floor amendment in November 1983 and was accepted in the House-Senate conference on S. 540. Creating this new institute was intended to provide opportunities for nurses to participate in research conducted and supported by the National Institutes of Health. In response to the 1983 Institute of Medicine study which identified the need to establish an organizational entity for nursing research, the House chose legislation which would establish a new institute at NIH. The Committee supports the intent of this effort: That is, to increase federal support for nursing research and provide more visibility for qualified nursing researchers. However, the Committee believes the proposal for the new institute is premature and that possible funding may not be sufficient to accomplish the stated goals. The committee has chosen to work with representatives of the nursing profession and the Administration to develop an alternative proposal which will place nursing research in the mainstream of scientific investigation. We are convinced that a substantial share of our health care dollars could be saved if research related to improved patient care, patient education, and health promotion were substantially supported. Furthermore, nurses play a vital role in the delivery of health care in many underserved areas and should play a major role in health services research. Therefore, this bill does not authorize creation of a National Institute of Nursing, but the Committee looks forward to working with our colleagues in the Senate and House, and particularly with Congressman Madigan, who has

been such a stalwart champion of nursing research, to improve federal support for this effort.

Inasmuch as this legislation is identical, with respect to provisions relating to fetal research and biomedical ethics, with the bill approved by Congress last year, the following excerpts from the report accompanying S. 540 (Report 98–1155) continue to convey the sense of the Committee on these important issues.

(1) Ethics Advisory Commission: ". . . change the ethics advisory committee located in the Office of Technology Assessment (OTA) in the Senate bill into an independent Congressional Ethics Advisory Commission patterned after the OTA. The Commission would examine a broad range of biomedical issues and report to the Congress and the public. Two studies are specifically mandated in the legislation: (1) an examination of the nature, advisability, and biomedical and ethical implications of exercising any waiver of existing Federal protections of human fetuses in research and (2) a study of the ethical implications of developments in genetic engineering for human genetic engineering."

(2) Fetal research: ". . . includes provisions to define the circumstances under which research involving living human fetuses may be conducted.

In the case of living human nonviable fetuses ex utero or living human fetuses for whom viability has not yet been determined, the Secretary may support only those research projects that (1) may enhance the well-being or meet the health needs of the fetus, (2) enhance the probability of the fetus' survival to viability, or (3) whose purpose is to develop important biomedical knowledge that cannot be obtained by other means and that will pose no added risk of suffering, injury, or death to the fetus. This standard is to be equally applied to fetuses that are aborted spontaneously or by induced abortion. It is not the intention . . . that the phrase "no added risk of suffering" be construed to restrict routine diagnostic or medical procedures, such as the drawing of blood, that may themselves involve transient pain but pose no risk to the fetus of long-term suffering or injury.

In the case of living human fetuses in utero, the agreement requires that the Secretary administer regulations regarding the standard of risk in such a manner that a fetus that is intended for abortion is exposed to no greater risk than that to which a fetus that is intended to be carried to term may be exposed.

The . . . agreement further provides that the Biomedical Ethics Advisory Committee, created by this legislation, is to conduct a study of the nature, advisability, and biomedical and ethical implications of exercising any waiver of the current "minimal risk" standard (or any successor to this standard) in research involving fetuses. The Committee is to complete its report within thirty months of the enactment of this legislation and shall report its findings to the Biomedical Ethics Board. The Board is to transmit the Committee's report to the Secretary, as well as the Senate Committee on Labor and Human Resources and the House Committee on Energy and Commerce. . . . note that while the charge to the Committee is limited under this provision, the Committee is empowered under other provisions of this legislation to review and

investigate other issues involving the protection of human subjects, including fetuses.

The . . . agreement also prohibits the Secretary from granting a waiver of the requirements of current regulations regarding research that is of unknown or greater-than-minimal risk. In addition, the . . . agreement does not prohibit the Secretary from revising any regulations in effect on the day prior to the enactment of this legislation, including the waiver provision." The prohibition is intended to last for three years and is repealed as of October 31, 1988.

In summary, the Committee strongly supports the research effort conducted by, and through, our National Institutes of Health. This bill authorizes generous appropriations for the two largest institutes, the National Cancer Institute and the National Heart, Lung, and Blood Institute. It creates a National Institute of Arthritis and Musculoskeletal and Skin Diseases, and a National Institute of Diabetes and Digestive and Kidney Diseases. It also requires time-limited studies or commissions to advise or research priorities in areas of significant public concern, and provides a means of dealing with ongoing concerns about ethical issues in biomedical research. The bill has been modified to address concerns conveyed by the Administraton. The Committee commends this legislation to our colleagues in the Senate for expeditious approval.

Miscellaneous Concerns or Comments

(1) MARY BABB RANDOLPH CANCER CENTER

The Committee recognizes the lack of organized state-of-the-art cancer research and treatment in the Appalachia region. It is estimated that about one-third of those West Virginians dying from cancer might have been saved by earlier diagnosis and treatment. The lack of organized statewide approaches to cancer prevention, detection, and accessibility to specialized care underscores the need for an academically based cancer program for the State of West Virginia and the region of Appalachia that it would serve. The Committee supports the establishment of such a center at West Virginia University.

(2) NIH TASK FORCE ON NURSING RESEARCH

The Committee would like to recognize the excellent work done by the NIH Task Force on Nursing Research, chaired by Dr. Frank Williams, Director on the National Institute on Aging. The scope of the study, recommendations provided, and the implementation plan indicate a positive response to the Institute of Medicine's study on nursing research.

(3) FRAUDULENT USE OF NIH GRANT FUNDS

The Committee continues to hear of fraudulent and wasteful use of NIH grant and contract monies. Senator Hawkins highlighted those problems in the 98th Congress and amended the NIH authorizing bill to require improvements in grants management and a report on efforts make to stem fraudulent activities. However, as the competition for funds increases in the scientific community,

and the resources become more limited relative to the number of applicants, the temptation to falsify data and misrepresent claims of success seems to persist. Individuals have provided what they feel is evidence of misspent federal funds nationwide, and we believe such claims merit investigation to determine how we can minimize waste, abuse, and fiscal fraud.

(4) BRAIN INFORMATION SERVICE AT UCLA

The Committee again encourages the Director of NIH to develop and implement a cooperative funding plan among appropriate Institutes to continue the activities of the Brain Information Service and reaffirms its belief that the Brain Information Service should be supported as resources permit.

(5) ANIMAL WELFARE

Changes in the law have been made to improve laboratory care and treatment of animals used for research. The Committee believes these changes are important to address concerns expressed by a growing number of our citizens about inhumane and unnecessary use of animals in research. In fact, the Committee does not intend that the language in Section 493(e) of this bill be interpreted to inhibit government investigations into allegations of improper care or use of laboratory animals. Such investigations may be required to assure compliance with the provisions of Section 493.

(6) INDIRECT COSTS

The Committee believes that a fair and rational national policy should be established to limit the amount of grant and contract funds used for indirect costs. Although universities need and deserve some support to conduct research, the amount of these indirect costs has grown so that it is out of proportion to the costs of conducting research. The Committee recommends a new effort to reevaluate the method of accounting required by OMB Circular A-21. The following quote from a recent interview with Bernadine Healy, M.D., Deputy Director of the White House Office of Science and Technology Policy, highlights the need for reform.

> The indirect cost issue is perhaps a symptom of strains between universities and the federal government. It is an issue which is complex and emotional. In the Health of the University study (being conducted by the White House Science Council) there are a number of issues being addressed. What is the nature of the relationship between the federal government and the universities? If you say it's a procurement arrangement that implies a great deal of things in terms of mutual responsibilites. If you say it's an investment it implies many other things. For example, it implies that the universities, in part, become federal institutions. I don't think private institutions like to hear that, but, what percentage of a research-intensive university's overhead costs—presidents, deans, lawyers, hot water, etc., are paid by the federal government? Approximately 50 percent. That's a staggering amount. There's a good reason

why universities are concerned about tampering with their overhead.

(7) RESEARCH IN DIAGNOSTIC IMAGING

The Committee notes that the National Cancer Institute has supported research on diagnostic imaging. The Committee would like to see the continuation by NCI of such research with consideration given to including studies of processes of visual perception and cognition by physicians who interpret imaging procedures; exploration of the potentials of non-ionizing radiation sources for imaging procedures; and basic and clinical applications of magnetic resonance techniques and, if appropriate, protocols for use of imaging.

(8) RESEARCH IN CHILD ABUSE AND NEGLECT

The Committee is concerned about the continuing increase in abuse, neglect, and sexual exploitation of children. The Committee encourages the National Institute of Child Health and Human Development to work with other interested federal departments and agencies to ensure appropriate funding of research into the long-term consequences of violence against infants and children, to develop a better understanding of the causes and consequences of child abuse and neglect.

REVIEW OF CONTRACTS

The Committee understands that at NIH the system for review of grants is necessarily different from that used for contracts. In addition, the Committee is aware that contract project plans are now thoroughly evaluated at early stages of development. The Committee does not intend in this legislation that peer review of contracts, after they have been solicited, negotiated, and signed, is necessarily required. In general, we recognize that peer review after completion of a contract would be unlikely to reveal deficiencies or correct weaknesses not identified in earlier review.

The Committee is well aware that, consistent with the intent of Congress, review of contract project concepts and well-defined, circumscribed, tasks is covered clearly under current Peer Review Regulations, which required that agency heads, including the Director of NIH, "identify individual contracts or classes of contracts which may not be awarded unless all pertinent contract proposals have been reviewed by a peer review group . . . ." The Committee further recognizes that NIH policy requires peer review of proposals for innovative approaches to stated requirements, but permits staff evaluations of the resources and technical capabilities of offerors to accomplish tasks that were already defined at the concept review stage.

(10) LEGISLATIVE AUTHORITY OF THE DIVISION OF RESEARCH RESOURCES

The Committee does not intend, by its listing of the Division of Research Resources (DRR) as an "entity" rather than an "institute" of NIH that the authority under which the DRR advisory council functions should differ from that for the advisory councils

of the NIH research institutes. The Committee understands that DRR operates a larger program of grants, contracts, and cooperative agreements and, like the research institutes, requires review by a national advisory council. The advisory council of DRR, established and functioning under Sections 202 and 222 of the Public Health Service Act, will continue to function in the same manner as other national advisory councils under this legislation, with authorities and responsibilities as described in section 406 of this bill.

(11) PRIMATE CENTERS

In the 98th Congress, the Committee accepted an amendment to one of its Public Health Service bills that would have required that the Laboratory for Experimental Medicine and Surgery in Primates (LEMSIP) be designated as a Regional Primate Research Center. The Committee continues to encourage NIH to give full consideration to proposals from LEMSIP for such designation. LEMSIP's international acclaim, demonstrated humane treatment of primates, and unique blood grouping programs are good reasons for this institution to be included in the primate research program. The Committee looks forward to an early report from NIH regarding the status of LEMSIP's inclusion in this national program.

(12) NIH ADMINISTRATIVE EXPENSES

The Committee recognizes that there is concern about NIH administrative expenses, especially with respect to potential increases of such expenses as a result of the establishment of a new research institute. In particular, the percentage that administrative costs represent compared with total expenditures has been a matter for concern. It is for this reason that the bill requires a study by NIH of this matter. The Committee believes that such a study is an appropriate way to resolve these concerns.

(13) DIET THERAPY FOR KIDNEY DISEASE

The Committee recognizes that progress has been made in this area. The National Institute of Arthritis, Diabetes, and Digestive and Kidney Diseases (NIADDK) and the Health Care Financing Administration are collaborating on a clinical study of the influence of dietary modification on the progression of chronic renal disease. The plannig phase of this study is being completed and the pilot study is commencing. NIADDK is submitting a call for proposals to include children in this study. In addition, consideration of the exact supplement for the very-low-protein diet to be used in the study has been extensively evaluated at two levels of scientific and medical review and the use of both essential amino acid and ketoacid supplementation has received unanimous agreement. The costs of ketoacid and amino acid supplementation appear to be equivalent.

(14) ANTI-HORMONE CANCER THERAPY

The Committee recognizes the progress made in anti-hormone research and therapy at the National Cancer Institute and would urge that increased effort and resources be devoted to such work.

The Committee is particularly interested in pursuing the feasibility of a wider application of this therapy to other types of cancer.

VI. Text of S. 1309 as Reported

A BILL To amend the Public Health Service Act to revise and extend the authorities under that Act relating to the National Institutes of Health and National Research Institutes, and for other purposes.

Be it enacted by the Senate and House of Representatives of the United States of America in Congress assembled,

SHORT TITLE; REFERENCE TO ACT; AND TABLE OF CONTENTS

SECTION 1. (a) This Act may be cited as the "Health Research Extension Act of 1985".

(b) Except as otherwise specifically provided, whenever in this Act an amendment or repeal is expressed in terms of an amendment to, or repeal of, a section or other provision, the reference shall be considered to be a reference to a section or other provision of the Public Health Service Act.

TABLE OF CONTENTS

Sec. 1. Short title; reference to Act; and table of contents.
Sec. 2. Revision of title IV of the Public Health Service Act.

"TITLE IV—NATIONAL RESEARCH INSTITUTES

"PART A—NATIONAL INSTITUTES OF HEALTH

"Sec. 401. Organization of the National Institutes of Health.
"Sec. 402. Appointment and authority of Director of NIH.
"Sec. 403. Report of Director of NIH.

"PART B—GENERAL PROVISIONS RESPECTING NATIONAL RESEARCH INSTITUTES

"Sec. 405. Appointment and authority of the Directors of the National Research Institutes.
"Sec. 406. Advisory councils.
"Sec. 407. Biennial report.
"Sec. 408. Authorizations of appropriations.

"PART C—SPECIFIC PROVISIONS RESPECTING NATIONAL RESEARCH INSTITUTES

"SUBPART 1—NATIONAL CANCER INSTITUTE

"Sec. 410. Purpose of Institute.
"Sec. 411. National cancer program.
"Sec. 412. Cancer control programs.
"Sec. 413. Special authorities of the Director.
"Sec. 414. National cancer research and demonstration centers.
"Sec. 415. President's cancer panel.
"Sec. 416. Associate Director for Prevention.

"SUBPART 2—NATIONAL HEART, LUNG, AND BLOOD INSTITUTE

"Sec. 418. Purpose of the Institute.
"Sec. 419. Heart, blood vessel, lung, and blood disease prevention and control programs.
"Sec. 420. Information and education.
"Sec. 421. National heart, blood vessel, lung, and blood diseases and blood resources program.
"Sec. 422. National research and demonstration centers for heart, blood vessel, lung, and blood diseases, sickle cell anemia, and blood resources.
"Sec. 423. Interagency technical committee.
"Sec. 424. Associate Director for Prevention.

"SUBPART 3—NATIONAL INSTITUTE OF DIABETES AND DIGESTIVE AND KIDNEY DISEASES

"Sec. 426. Purpose of the Institute.
"Sec. 427. Data systems and information clearinghouses.
"Sec. 428. Division Directors for diabetes, endocrinology, and metabolic diseases, digestive diseases and nutrition, and kidney, urologic, and hematologic diseases.
"Sec. 429. Interagency coordinating committees.
"Sec. 430. Advisory boards.
"Sec. 431. Research and training centers.
"Sec. 432. Advisory council subcommittees.
"Sec. 433. Biennial report.

"SUBPART 4—NATIONAL INSTITUTE OF ARTHRITIS AND MUSCULOSKELETAL AND SKIN DISEASES

"Sec. 435. Purpose of the Institute.
"Sec. 436. National arthritis and musculoskeletal diseases program.
"Sec. 437. Research and training.
"Sec. 438. Data systems and information clearinghouses.
"Sec. 439. Interagency coordinating committees.
"Sec. 440. Arthritis and musculoskeletal diseases demonstration projects.
"Sec. 441. Multipurpose arthritis and musculoskeletal diseases centers.
"Sec. 442. Advisory board.

"SUBPART 5—NATIONAL INSTITUTE ON AGING

"Sec. 443. Purpose of the Institute.
"Sec. 444. Special functions.
"Sec. 445. Alzheimer's Disease Centers.

"SUBPART 6—NATIONAL INSTITUTE OF ALLERGY AND INFECTIOUS DISEASES

"Sec. 446. Purpose of the Institute.

"SUBPART 7—NATIONAL INSTITUTE OF CHILD HEALTH AND HUMAN DEVELOPMENT

"Sec. 448. Purpose of the Institute.
"Sec. 449. Sudden infant death syndrome.
"Sec. 450. Mental retardation research centers.
"Sec. 451. Associate Director for Prevention.

"SUBPART 8—NATIONAL INSTITUTE OF DENTAL RESEARCH

"Sec. 453. Purpose of the Institute.

"SUBPART 9—NATIONAL EYE INSTITUTE

"Sec. 455. Purpose of the Institute.

"SUBPART 10—NATIONAL INSTITUTE OF NEUROLOGICAL AND COMMUNICATIVE DISORDERS AND STROKE

"Sec. 457. Purpose of the Institute.
"Sec. 458. Spinal cord regeneration research.
"Sec. 459. Bioengineering research.

"SUBPART 11—NATIONAL INSTITUTE OF GENERAL MEDICAL SCIENCES

"Sec. 461. Purpose of the Institute.

"SUBPART 12—NATIONAL INSTITUTE OF ENVIRONMENTAL HEALTH SCIENCES

"Sec. 463. Purpose of the Institute.

"PART D—NATIONAL LIBRARY OF MEDICINE

"SUBPART 1—GENERAL PROVISIONS

"Sec. 467. Purpose and establishment of the Library.
"Sec. 468. Functions of the Library.
"Sec. 469. Board of Regents.
"Sec. 470. Library facilities.

"SUBPART 2—FINANCIAL ASSISTANCE

"Sec. 472. Authorization of appropriations.
"Sec. 473. Definitions.
"Sec. 474. National Medical Libraries Assistance Board.
"Sec. 475. Grants for training in medical library sciences.
"Sec. 476. Assistance for special scientific projects, and for research and development in medical library science and related fields.
"Sec. 477. Grants for establishing, expanding, and improving the basic resources of medical libraries and related instrumentalities.
"Sec. 478. Grants and contracts for establishment of regional medical libraries.
"Sec. 479. Financial support of biomedical scientific publications.
"Sec. 480. Grant payments; records and audit.

"PART E—OTHER AGENCIES OF NIH

"Sec. 482. Division of Research Resources.
"Sec. 483. John E. Fogarty International Center for Advanced Study in the Health Sciences.

"PART F—AWARDS AND TRAINING

"Sec. 485. National research service awards.
"Sec. 486. Visiting scientist awards.
"Sec. 487. Studies respecting biomedical and behavioral research personnel.

"PART G—GENERAL PROVISIONS

"Sec. 489. Institutional review boards; ethics guidance program.
"Sec. 490. Peer review requirements.
"Sec. 491. Protection against scientific fraud.
"Sec. 492. Research on public health emergencies.
"Sec. 493. Animals in research.
"Sec. 494. Use of appropriations under this title.
"Sec. 495. Gifts.
"Sec. 496. Fetal Research.
"Sec. 497. Construction of title.".
Sec. 3. Conforming amendments.
Sec. 4. Plan for research involving animals.
Sec. 5. Research on lupus erythematosus.
Sec. 6. National Research Service Award study.
Sec. 7. Interagency Committee on Spinal Cord Injury.
Sec. 8. Study of personnel for health needs of elderly.
Sec. 9. Interagency Committee on Learning Disabilities.
Sec. 10. Review of disease research programs of the National Institute of Diabetes and Digestive and Kidney Diseases.
Sec. 11. Biomedical ethics.
Sec. 12. Effective date.

REVISION OF TITLE IV OF THE PUBLIC HEALTH SERVICE ACT

SEC. 2. Title IV of the Public Health Service Act is amended to read as follows:

"TITLE IV—NATIONAL RESEARCH INSTITUTES

"PART A—NATIONAL INSTITUTES OF HEALTH

"ORGANIZATION OF THE NATIONAL INSTITUTES OF HEALTH

"SEC. 401. (a) The National Institutes of Health is an agency of the Service.

"(b)(1) The following national research institutes are agencies of the National Institutes of Health:

"(A) The National Cancer Institute.

"(B) The National Heart, Lung, and Blood Institute.

"(C) The National Institute of Diabetes and Digestive and Kidney Diseases.

"(D) The National Institute of Arthritis and Musculoskeletal and Skin Diseases.

"(E) The National Institute on Aging.

"(F) The National Institute of Allergy and Infectious Diseases.

"(G) The National Institute of Child Health and Human Development.

"(H) The National Institute of Dental Research.

"(I) The National Eye Institute.

"(J) The National Institute of Neurological and Communicative Disorders and Stroke.

"(K) The National Institute of General Medical Sciences.

"(L) The National Institute of Environmental Health Sciences.

"(2) The following entities are agencies of the National Institutes of Health:

"(A) The National Library of Medicine.

"(B) The Division of Research Resources.

"(C) The John E. Fogarty International Center for Advanced Study in the Health Sciences.

"(c)(1) The Secretary may establish in the National Institutes of Health one or more additional national research institutes to conduct and support research, training, health information, and other programs with respect to any particular disease or groups of diseases or any other aspect of human health if—

"(A) the Secretary determines that an additional institute is necessary to carry out such activities; and

"(B) the additional institute is not established before the expiration of 90 days after the Secretary has provided the Committee on Energy and Commerce of the House of Representatives and the Committee on Labor and Human Resources of the Senate written notice of the determination made under clause (i) with respect to the institute.

"(2) The Secretary may reorganize the functions of any national research institute and may abolish any national research institute if the Secretary determines that the institute is no longer required. A reorganization or abolition may not take effect under this subparagraph before the expiration of 90 days after the Secretary has provided the Committee on Energy and Commerce of the House of Representatives and the Committee on Labor and Human Resources of the Senate written notice of the reorganization or abolition.

"(d) For purposes of this title, the term 'national research institute' means a national research institute listed in subsection (b) or established under subsection (c). A reference to the National Institutes of Health includes its agencies.

"APPOINTMENT AND AUTHORITY OF DIRECTOR OF NIH

"SEC. 402. (a) The National Institutes of Health shall be headed by the Director of the National Institutes of Health (hereafter in this title referred to as the 'Director of NIH') who shall be appoint-

ed by the President by and with the advice and consent of the Senate. The Director of NIH shall perform functions as provided under subsection (b) and as the Secretary may otherwise prescribe.

"(b) In carrying out the purposes of section 301, the Secretary, acting through the Director of NIH—

"(1) shall be responsible for the overall direction of the National Institutes of Health and for the establishment and implementation of general policies respecting the management and operation of programs and activities within the National Institutes of Health;

"(2) shall coordinate and oversee the operation of the national research institutes and administrative entities within the National Institutes of Health;

"(3) shall assure that research at the National Institutes of Health is subject to review in accordance with sections 405(c)(3) and 490(b);

"(4) for the national research institutes and administrative entities within the National Institutes of Health—

"(A) may acquire, construct, improve, repair, operate, and maintain, at the site of such institutes and entities, laboratories, and other research facilities, other facilities, equipment, and other real or personal property, and

"(B) may acquire, without regard to the Act of March 3, 1877 (40 U.S.C. 34), by lease or otherwise through the Administrator of General Services, buildings or parts of buildings in the District of Columbia or communities located adjacent to the District of Columbia for use for a period not to exceed ten years;

"(5) may secure resources for research conducted by or through the National Institutes of Health;

"(6) may, without regard to the provisions of title 5, United States Code, governing appointments in the competitive service, and without regard to the provisions of chapter 51 and subchapter III of chapter 53 of such title relating to classification and General Schedule pay rates, establish such technical and scientific peer review groups as are needed to carry out the requirements of this title and appoint and pay the members of such groups, except that officers and employees of the United States shall not receive additional compensation for service as members of such groups;

"(7) may secure for the National Institutes of Health consultation services and advice of persons from the United States or abroad;

"(8) may use, with their consent, the services, equipment, personnel, information, and facilities of other Federal, State, or local public agencies, with or without reimbursement therefor;

"(9) may, for purposes of study, admit and treat at facilities of the National Institutes of Health individuals not otherwise eligible for such treatment;

"(10) may accept voluntary and uncompensated services; and

"(11) may perform such other administrative functions as the Secretary determines are needed to effectively carry out this title.

The Federal Advisory Committee Act shall not apply to any peer review group appointed under paragraph (6). The members of such a group shall be individuals who by virtue of their training or experience are eminently qualified to perform the review functions of such group. Not more than one-fourth of the members of any such group shall be officers or employees of the United States.

"(c) The Director of NIH may make available to individuals and entities, for biomedical and behavioral research, substances and living organisms. Such substances and organisms shall be made available under such terms and conditions (including payment for them) as the Secretary determines appropriate.

"(d)(1) The Director of NIH may obtain (in accordance with section 3109 of title 5, United States Code, but without regard to the limitation in such section on the period of service) the services of not more than two hundred experts or consultants, with scientific or other professional qualifications, for the National Institutes of Health.

"(2)(A) Except as provided in subparagraph (B), experts and consultants whose services are obtained under paragraph (1) shall be paid or reimbursed, in accordance with title 5, United States Code, for their travel and other expenses associated with their assignment.

"(B) Expenses specified in subparagraph (A) shall not be allowed in connection with the assignment of an expert or consultant whose services are obtained under paragraph (1) unless the expert or consultant has agreed in writing to complete the entire period of the assignment or one year of the assignment, whichever is shorter, unless separated or reassigned for reasons which are beyond the control of the expert or consultant and which are acceptable to the Secretary. If the expert or consultant violates the agreement, the money spent by the United States for such expenses is recoverable from the expert or consultant as a debt due the United States. The Secretary may waive in whole or in part a right of recovery under this subparagraph.

"(e) The Director of NIH shall—

"(1) advise the agencies of the National Institutes of Health on medical applications of research;

"(2) coordinate, review, and facilitate the systematic identification and evaluation of, clinically relevant information from research conducted by or through the national research institutes;

"(3) promote the effective transfer of the information described in paragraph (2) to the health care community and to entities that require such information; and

"(4) monitor the effectiveness of the activities described in paragraph (3).

"(f) There shall be in the National Institutes of Health an Associate Director for Prevention. The Director of NIH shall delegate to the Associate Director for Prevention the functions of the Director relating to the promotion of the disease prevention research programs of the national research institutes and the coordination of such programs among the national research institutes and between the national research institutes and other public and private entities. The Associate Director shall annually report to the Director of

NIH on the prevention activities undertaken by the Associate Director. The report shall include a detailed statement of the expenditures made for the activities reported on and the personnel used in connection with such activities.

"REPORT OF DIRECTOR OF NIH

"SEC. 403. The Secretary shall transmit to the President and to the Congress a biennial report which shall be prepared by the Director of NIH and which shall consist of—

"(1) a description of the activities carried out by and through the National Institutes of Health and the policies respecting the programs of the National Institutes of Health and such recommendations respecting such policies as the Secretary considers appropriate;

"(2) a description of the activities undertaken to improve grants and contracting accountability and peer review procedures of the National Institutes of Health and the national research institutes;

"(3) the reports made by the Associate Director for Prevention under section 402(f) during the period for which the biennial report is prepared; and

"(4) the biennial reports of the Directors of each of the national research institutes.

The first report under this section shall be submitted not later than April 1, 1986, and shall relate to the fiscal year ending on the preceding September 30. The next report shall be submitted not later than December 30, 1988, and shall relate to the two-fiscal-year period ending on the preceding September 30. Each subsequent report shall be submitted not later than 90 days after the end of the two-fiscal-year period for which the report is to be submitted.

"PART B—GENERAL PROVISIONS RESPECTING NATIONAL RESEARCH INSTITUTES

"APPOINTMENT AND AUTHORITY OF THE DIRECTORS OF THE NATIONAL RESEARCH INSTITUTES

"SEC. 405. (a) The Director of the National Cancer Institute shall be appointed by the President and the Directors of the other national research institutes shall be appointed by the Secretary. Each Director of a national research institute shall report directly to the Director of NIH.

"(b)(1) In carrying out the purposes of section 301 with respect to the human diseases or disorders or other aspects of human health for which the national research institutes were established, the Secretary, acting through the Director of each national research institute—

"(A) shall encourage and support research, investigations, experiments, demonstrations, and studies in the health sciences related to—

"(i) the maintenance of health,

"(ii) the detection, diagnosis, treatment, and prevention of human diseases and disorders,

"(iii) the rehabilitation of individuals with human diseases, disorders, and disabilities, and

"(iv) the expansion of knowledge of the processes underlying human diseases, disorders, and disabilities, the processes underlying the normal and pathological functioning of the body and its organ systems, and the processes underlying the interactions between the human organism and the environment;

"(B) may, subject to the peer review prescribed under section 490(b) and any advisory council review under section 406(a)(3)(A)(i), conduct the research, investigations, experiments, demonstrations, and studies referred to in subparagraph (A);

"(C) may conduct and support research training (i) for which fellowship support is not provided under section 485, and (ii) which is not residency training of physicians or other health professionals;

"(D) may develop, implement, and support demonstrations and programs for the application of the results of the activities of the institute to clinical practice and disease prevention activities;

"(E) may develop, conduct, and support public and professional education and information programs;

"(F) may secure, develop and maintain, distribute, and support the development and maintenance of resources needed for research;

"(G) may make available the facilities of the institute to appropriate entities and individuals engaged in research activities and cooperate with and assist Federal and State agencies charged with protecting the public health;

"(H) may accept unconditional gifts made to the institute for its activities, and, in the case of gifts of a value in excess of $50,000, establish suitable memorials to the donor;

"(I) may secure for the institute consultation services and advice of persons from the United States or abroad;

"(J) may use, with their consent, the services, equipment, personnel, information, and facilities of other Federal, State, or local public agencies, with or without reimbursement therefor;

"(K) may accept voluntary and uncompensated services; and

"(L) may perform such other functions as the Secretary determines are needed to carry out effectively the purposes of the institute.

The indemnification provisions of section 2354, title 10, United States Code, shall apply with respect to contracts entered into under this subsection and section 402(b).

"(2) Support for an activity or program under this subsection may be provided through grants, contracts, and cooperative agreements. The Secretary, acting through the Director of each national research institute—

"(A) may enter into a contract for research, training, or demonstrations only if the contract has been recommended after peer review required by regulations under section 490; and

"(B) may make grants and cooperative agreements under paragraph (1) for research, training, or demonstrations, except that—

"(i) if the direct cost of the grant or cooperative agreement to be made does not exceed $50,000, such grant or cooperative agreement may be made only if such grant or cooperative agreement is recommended after peer review required by regulations under section 490, and

"(ii) if the direct cost of the grant or cooperative agreement to be made equals or exceeds $50,000, such grant or cooperative agreement may be made only if such grant or cooperative agreement is recommended after peer review required by regulations under section 490 and is recommended under section 406(a)(3)(A)(ii) by the advisory council for the national research institute involved.

"(c) In carrying out subsection (b), each Director of a national research institute—

"(1) shall coordinate, as appropriate, the activities of the institute with similar programs of other public and private entities;

"(2) shall cooperate with the Directors of the other national research institutes in the development and support of multidisciplinary research and research that involves more than one institute; and

"(3) may, with the approval of the advisory council for the institute and the Director of NIH, appoint peer review groups in addition to those appointed under section 402(b)(6).

"ADVISORY COUNCILS

"SEC. 406. (a)(1) Except as provided in subsection (h), the Secretary shall appoint an advisory council for each national research institute which (A) shall advise, assist, consult with, and make recommendations to the Secretary and the Director of such institute on matters related to the activities carried out by and through the institute and the policies respecting such activities, and (B) shall carry out the special functions prescribed by part C.

"(2) Each advisory council for a national research institute may recommend to the Secretary acceptance, in accordance with section 2101, of conditional gifts for study, investigation, or research respecting the diseases, disorders, or other aspect of human health with respect to which the institute was established, for the acquisition of grounds, or for the construction, equipping, or maintenance of facilities for the institute.

"(3) Each advisory council for a national research institute—

"(A)(i) may on the basis of the materials provided under section 490(b)(2) respecting research conducted at the institute, make recommendations to the Director of the institute respecting such research,

"(ii) may review applications for grants and cooperative agreements for research or training and for which advisory council approval is required under section 405(b)(2) and recommend for approval applications for projects which show promise of making valuable contributions to human knowledge, and

"(iii) may review any grant, contract, or cooperative agreement proposed to be made or entered into by the institute;

"(B) may collect, by correspondence or by personal investigation, information as to studies which are being carried on in the United States or any other country as to the disease, disorders, or other aspect of human health with respect to which the institute was established and with the approval of the Director of the institute make available such information through appropriate publications for the benefit of public and private health entities and health professions personnel and scientists and for the information of the general public; and

"(C) may appoint subcommittees and convene workshops and conferences.

"(b)(1) Each advisory council shall consist of ex officio members and not more than eighteen members appointed by the Secretary.

"(2) The ex officio members of an advisory council shall consist of—

"(A) the Secretary, the Director of NIH, the Director of the national research institute for which the council is established, the Chief Medical Director or the Chief Dental Director of the Veterans' Administration, and the Assistant Secretary of Defense for Health Affairs (or the designees of such officers); and

"(B) such additional officers or employees of the United States as the Secretary determines necessary for the advisory council to effectively carry out its functions.

"(3) The members of an advisory council who are not ex officio members shall be appointed as follows:

"(A) Two thirds of the members shall be appointed by the Secretary from among the leading representatives of the health and scientific disciplines relevant to the activities of the national research institute for which the advisory council is established.

"(B) One third of the members shall be appointed by the Secretary from the general public and from among leaders in fields of public health, behavioral science, social science, public policy, law, health policy, economics, and management, and at least one of such members shall be from the general public.

"(4) Members of an advisory council who are officers or employees of the United States shall not receive any compensation for service on the advisory council. The other members of an advisory council shall receive, for each day (including traveltime) they are engaged in the performance of the functions of the advisory council, compensation at rates not to exceed the daily equivalent of the annual rate in effect for grade GS–18 of the General Schedule.

"(c) The term of office of an appointed member of an advisory council is four years, except that any member appointed to fill a vacancy for an unexpired term shall be appointed for the remainder of such term and the Secretary shall make appointments to an advisory council in such a manner as to ensure that the terms of the members do not all expire in the same year. A member may serve after the expiration of the member's term until a successor has taken office. A member who has been appointed for a term of four years may not be reappointed to an advisory council before two years from the date of expiration of such term of office. If a

vacancy occurs in the advisory council among the appointed members, the Secretary shall make an appointment to fill the vacancy within 90 days from the date the vacancy occurs.

"(d) The chairman of an advisory council shall be the Director of the national research institute for which the advisory council is established.

"(e) The advisory council shall meet at the call of the chairman or upon the request of the Director of the national research institute for which it was established, but at least three times each fiscal year. The location of the meetings of each advisory council is subject to the approval of the Director of the national research institute for which the advisory council was established.

"(f) The Director of the national research institute for which an advisory council is established shall designate a member of the staff of the institute to serve as the executive secretary of the advisory council. The Director of such institute shall make available to the advisory council such staff, information, and other assistance as it may require to carry out its functions. The Director of such institute shall provide orientation and training for new members of the advisory council to provide them with such information and training as may be appropriate for their effective participation in the functions of the advisory council.

"(g) Each advisory council may prepare, for inclusion in the biennial report made under section 407, (1) comments respecting the activities of the advisory council in the fiscal years respecting which the report is prepared, (2) comments on the progress of the national research institute for which it was established in meeting its objectives, and (3) recommendations respecting the future directions and program and policy emphasis of the institute. Each advisory council may prepare such additional reports as it may determine appropriate.

"(h)(1) Except as provided in paragraph (2), this section does not terminate the membership of any advisory council for a national research institute which was in existence on the effective date of the Health Research Extension Act of 1985. After such date—

"(A) the Secretary shall make appointments to each such advisory council in such a manner as to bring about as soon as practicable the composition for such council prescribed by this section;

"(B) each advisory council shall organize itself in accordance with this section and exercise the functions prescribed by this section; and

"(C) the Director of each national research institute shall perform for such advisory council the functions prescribed by this section.

"(2)(A) The National Cancer Advisory Board shall be the advisory council for the National Cancer Institute. This section applies to the National Cancer Advisory Board, except that—

"(i) appointments to such Board shall be made by the President;

"(ii) the term of office of an appointed member shall be 6 years;

"(iii) of the members appointed to the Board, not less than five members shall be individuals knowledgeable in environ-

mental carcinogenesis (including carcinogenesis involving occupational and dietary factors);

"(iv) the chairman of the Board shall be selected by the President from the appointed members and shall serve as chairman for a term of two years;

"(v) the ex officio members of the Board shall be the Secretary, the Director of the Office of Science and Technology Policy, the Director of NIH, the Chief Medical Director of the Veterans' Administration, the Director of the National Institute for Occupational Safety and Health, the Director of the National Institute of Environmental Health Sciences, the Secretary of Labor, the Commissioner of the Food and Drug Administration, the Administrator of the Environmental Protection Agency, the Chairman of the Consumer Product Safety Commission, and the Assistant Secretary of Defense for Health Affairs (or the designees of such officers); and

"(vi) the Board shall meet at least four times each fiscal year.

"(B) This section applies to the advisory council to the National Heart, Lung, and Blood Institute, except that such advisory council shall meet at least four times each fiscal year.

"BIENNIAL REPORT

"SEC. 407. The Director of each national research institute, after consultation with the advisory council for the institute, shall prepare for inclusion in the biennial report made under section 403 a biennial report which shall consist of a description of the activities of the institute and program policies of the Director of the institute in the fiscal years respecting which the report is prepared. The Director of each national research institute may prepare such additional reports as the Director determines appropriate. The Director of each national research institute shall provide the advisory council for the institute an opportunity for the submission of the written comments referred to in section 406(g).

"AUTHORIZATIONS OF APPROPRIATIONS

"SEC. 408. (a) In addition to amounts otherwise authorized to be appropriated under this title for the National Institutes of Health, the following amounts are authorized to be appropriated:

"(1)(A) For the National Cancer Institute (other than its programs under section 412), there are authorized to be appropriated $1,194,000,000 for fiscal year 1986, $1,270,000,000 for fiscal year 1987, and $1,344,000,000 for fiscal year 1988.

"(B) For the programs under section 412, there are authorized to be appropriated $68,000,000 for fiscal year 1986, $74,000,000 for fiscal year 1987, and $80,000,000 for fiscal year 1988.

"(2)(A) For the National Heart, Lung, and Blood Institute (other than its programs under section 419), there are authorized to be appropriated $809,000,000 for fiscal year 1986, $871,000,000 for fiscal year 1987, and $927,000,000 for fiscal year 1988. Of the amount appropriated under this subsection for any such fiscal year, not less than 15 percent of such

amount shall be reserved for programs respecting diseases of the lung and not less than 15 percent of such amount shall be reserved for programs respecting blood diseases and blood resources.

"(B) For the programs under section 419, there are authorized to be appropriated $82,000,000 for fiscal year 1986, $90,000,000 for fiscal year 1987, and $98,000,000 for fiscal year 1988.

"(b)(1) Not later than December 31, 1987, and December 31 of each succeeding year, the Secretary shall report to the Congress the amount obligated in the fiscal year preceding such date for administrative expenses of the National Institutes of Health and the total amount appropriated for the National Institutes of Health for such fiscal year. The Secretary shall consult with the Comptroller General in preparing each report.

"(2) For purposes of paragraph (1), the term 'administrative expenses' means expenses incurred for the support of activities relevant to the award of grants, contracts, and cooperative agreements, and expenses incurred for general administration of the scientific programs and activities of the National Institutes of Health. In identifying expenses incurred for such support and administration, the Secretary shall consult with the Comptroller General of the United States.

"PART C--SPECIFIC PROVISIONS RESPECTING NATIONAL RESEARCH INSTITUTES

"Subpart 1—National Cancer Institute

"PURPOSE OF INSTITUTE

"SEC. 410. The general purpose of the National Cancer Institute (hereafter in this subpart referred to as the 'Institute') is the conduct and support of research, training, health information dissemination, and other programs with respect to the cause, diagnosis, prevention, and treatment of cancer and the continuing care of cancer patients and the families of cancer patients.

"NATIONAL CANCER PROGRAM

"SEC. 411. The National Cancer Program shall consist of (1) an expanded, intensified, and coordinated cancer research program encompassing the research programs conducted and supported by the Institute and the related research programs of the other national research institutes, including an expanded and intensified research program for the prevention of cancer caused by occupational or environmental exposure to carcinogens, and (2) the other programs and activities of the Institute.

"CANCER CONTROL PROGRAMS

"SEC. 412. The Director of the Institute shall establish and support demonstration, education, and other programs for the detection, diagnosis, prevention, and treatment of cancer and for rehabilitation and counseling respecting cancer. Programs established and supported under this section shall include—

"(1) locally initiated education and demonstration programs (and regional networks of such programs) to transmit research results and to disseminate information respecting—

"(A) the detection, diagnosis, prevention, and treatment of cancer,

"(B) the continuing care of cancer patients and the families of cancer patients, and

"(C) rehabilitation and counseling respecting cancer,

to physicians and other health professionals who provide care to individuals who have cancer;

"(2) the demonstration of and the education of students of the health professions and health professionals in—

"(A) effective methods for the prevention and early detection of cancer and the identification of individuals with a high risk of developing cancer, and

"(B) improved methods of patient referral to appropriate centers for early diagnosis and treatment of cancer; and

"(3) the demonstration of new methods for the dissemination of information to the general public concerning the prevention, early detection, diagnosis, and treatment and control of cancer and information concerning unapproved and ineffective methods, drugs, and devices for the diagnosis, prevention, treatment, and control of cancer.

"SPECIAL AUTHORITIES OF THE DIRECTOR

"SEC. 413. (a) The Director of the Institute shall establish an information and education center to collect, identify, analyze, and disseminate on a timely basis, through publications and other appropriate means, to cancer patients and their families, physicians and other health professionals, and the general public, information on cancer research, diagnosis, prevention, and treatment (including information respecting nutrition programs for cancer patients and the relationship between nutrition and cancer). The Director of the Institute may take such action as may be necessary to insure that all channels for the dissemination and exchange of scientific knowledge and information are maintained between the Institute and other scientific, medical, and biomedical disciplines and organizations nationally and internationally.

"(b) The Director of the Institute in carrying out the National Cancer Program—

"(1) shall establish or support the large-scale production or distribution of specialized biological materials and other therapeutic substances for cancer research and set standards of safety and care for persons using such materials;

"(2) shall, in consultation with the advisory council for the Institute, support (A) research in the cancer field outside the United States by highly qualified foreign nationals which can be expected to benefit the American people, (B) collaborative research involving American and foreign participants, and (C) the training of American scientists abroad and foreign scientists in the United States;

"(3) shall, in consultation with the advisory council for the Institute, support appropriate programs of education (including

continuing education) and training in fundamental sciences and clinical disciplines in order to enable investigators, physicians, and allied health professionals to participate in clinical programs relating to cancer;

"(4) shall encourage and coordinate cancer research by industrial concerns where such concerns evidence a particular capability for such research;

"(5) may obtain (with the approval of the advisory council for the Institute and in accordance with section 3109 of title 5, United States Code, but without regard to the limitation in such section on the period of service) the services of not more than one hundred and fifty-one experts or consultants who have scientific or professional qualifications;

"(6)(A) may, in consultation with the advisory council for the Institute, acquire, construct, improve, repair, operate, and maintain laboratories, other research facilities, equipment, and such other real or personal property as the Director determines necessary;

"(B) may, in consultation with the advisory council for the Institute, make grants for construction or renovation of facilities; and

"(C) may, in consultation with the advisory council for the Institute, acquire, without regard to the Act of March 3, 1877 (40 U.S.C. 34), by lease or otherwise through the Administrator of General Services, buildings or parts of buildings in the District of Columbia or communities located adjacent to the District of Columbia for the use of the Institute for a period not to exceed ten years;

"(7) may, in consultation with the advisory council for the Institute, appoint one or more advisory committees composed of such private citizens and officials of Federal, State, and local governments to advise the Director with respect to the Director's functions;

"(8) may, subject to section 405(b)(2) and without regard to section 3324 of title 31, United States Code, and section 3709 of the Revised Statutes (41 U.S.C. 5), enter into such contracts, leases, cooperative agreements, as may be necessary in the conduct of functions of the Director, with any public agency, or with any person, firm, association, corporation, or educational institution;

"(9) shall maintain and operate the International Cancer Research Data Bank, which shall collect, catalog, store, and disseminate insofar as feasible through the use of information systems accessible to the public, general practitioners, and oncologic investigators, the results of cancer research and treatment undertaken in any country for the use of any person involved in cancer research and treatment in any country; and

"(10)(A) shall, notwithstanding section 405(a), prepare and submit, directly to the President for review and transmittal to Congress, an annual budget estimate (including an estimate of the number and type of personnel needs for the Institute) for the National Cancer Program, after reasonable opportunity for comment (but without change) by the Secretary, the Director of NIH, and the Institute's advisory council; and (B) may re-

ceive from the President and the Office of Management and Budget directly all funds appropriated by Congress for obligation and expenditure by the Institute.

"(c) Except as otherwise provided, experts and consultants whose services are obtained under paragraph (5) of subsection (b) shall be paid or reimbursed, in accordance with title 5, United States Code, for their travel to and from their place of service and for other expenses associated with their assignment. Such expenses shall not be allowed in connection with the assignment of an expert or consultant whose services are obtained under such paragraph unless the expert or consultant has agreed in writing to complete the entire period of the assignment or one year of the assignment, whichever is shorter, unless separated or reassigned for reasons which are beyond the control of the expert or consultant and which are acceptable to the Director of the Institute. If the expert or consultant violates the agreement, the money spent by the United States for such expenses is recoverable from the expert or consultant as a debt due the United States. The Secretary may waiver in whole or in part a right of recovery under this subsection.

"NATIONAL CANCER RESEARCH AND DEMONSTRATION CENTERS

"SEC. 414. (a) The Director of the Institute is authorized to provide for the establishment of new centers for basic and clinical research into, training in, and demonstration of, advanced diagnostic, prevention, and treatment methods for cancer. Such centers may be supported under subsection (b) or under any other applicable provision of law.

"(b)(1) The Director of the Institute, under policies established by the Director of NIH and after consultation with the advisory council to the Institute, is authorized to enter into cooperative agreements with public or private nonprofit agencies or institutions to pay all or part of the cost of planning, establishing, or strengthening, and providing basic operating support for existing or new centers for basic and clinical research into, training in, and demonstration of advanced diagnostic, prevention, and treatment methods for cancer.

"(2) Federal payments made under this subsection in support of a cooperative agreement under paragraph (1) may be used for—

"(A) construction (notwithstanding any limitation under section 494);

"(B) staffing and other basic operating costs, including such patient care costs as are required for research;

"(C) clinical training, including training for allied health professionals, continuing education for health professionals and allied health professions personnel, and information programs for the public respecting cancer; and

"(D) demonstration purposes.

"(c) As used in this section, the term 'construction' does not include the acquisition of land, and the term 'training' does not include research training for which National Research Service Awards may be provided under section 485.

"(d) Support of a center under this section may be for a period of not to exceed five years. Such period may be extended by the Direc-

tor for additional periods of not more than five years each if the operations of such center have been reviewed by an appropriate scientific review group established by the Director and if such group has recommended to the Director that such period should be extended.

"PRESIDENT'S CANCER PANEL

"SEC. 415. (a)(1) The President's Cancer Panel (hereafter in this section referred to as the 'Panel') shall be composed of three persons appointed by the President who by virtue of their training, experience, and background are exceptionally qualified to appraise the National Cancer Program. At least two members of the Panel shall be distinguished scientists or physicians.

"(2)(A) Members of the Panel shall be appointed for three-year terms, except that (i) any member appointed to fill a vacancy occurring prior to the expiration of the term for which the member's predecessor was appointed shall be appointed only for the remainder of such term, and (ii) a member may serve until the member's successor has taken office. If a vacancy occurs in the Panel, the President shall make an appointment to fill the vacancy not later than 90 days after the date the vacancy occurred.

"(B) The President shall designate one of the members to serve as the chairman of the Panel for a term of one year.

"(C) Members of the Panel shall each be entitled to receive the daily equivalent of the annual rate of basic pay in effect for grade GS–18 of the General Schedule for each day (including traveltime) during which they are engaged in the actual performance of duties as members of the Panel and shall be allowed travel expenses (including a per diem allowance) under section 5703 of title 5, United States Code.

"(3) The Panel shall meet at the call of the chairman, but not less often than four times a year. A transcript shall be kept of the proceedings of each meeting of the Panel, and the chairman shall make such transcript available to the public.

"(b) The Panel shall monitor the development and execution of the activities of the National Cancer Program, and shall report directly to the President. Any delays or blockages in rapid execution of the Program shall immediately be brought to the attention of the President. The Panel shall submit to the President periodic progress reports on the Program and shall submit to the President, the Secretary, and the Congress an annual evaluation of the efficacy of the Program and suggestions for improvements, and shall submit such other reports as the President shall direct.

"ASSOCIATE DIRECTOR FOR PREVENTION

"SEC. 416. (a) There shall be in the Institute an Associate Director for Prevention to coordinate and promote the programs in the Institute concerning the prevention of cancer. The Associate Director shall be appointed by the Director of the Institute from individuals who because of their professional training or experience are experts in public health or preventive medicine.

"(b) The Associate Director for Prevention shall prepare for inclusion in the biennial report made under section 407 a description

of the prevention activities of the Institute, including a description of the staff and resources allocated to those activities.

"Subpart 2—National Heart, Lung, and Blood Institute

"PURPOSE OF THE INSTITUTE

"SEC. 418. The general purpose of the National Heart, Lung, and Blood Institute (hereafter in this subpart referred to as the 'Institute') is the conduct and support of research, training, health information dissemination, and other programs with respect to heart, blood vessel, lung, and blood diseases and with respect to the use of blood and blood products and the management of blood resources.

"HEART, BLOOD VESSEL, LUNG, AND BLOOD DISEASE PREVENTION AND CONTROL PROGRAMS

"SEC. 419. The Director of the Institute, under policies established by the Director of NIH and after consultation with the advisory council for the Institute, shall establish programs as necessary for cooperation with other Federal health agencies, State, local, and regional public health agencies, and nonprofit private health agencies in the diagnosis, prevention, and treatment (including the provision of emergency medical services) of heart, blood vessel, lung, and blood diseases, appropriately emphasizing the prevention, diagnosis, and treatment of such diseases of children.

"INFORMATION AND EDUCATION

"SEC. 420. The Director of the Institute shall collect, identify, analyze, and disseminate on a timely basis, through publications and other appropriate means, to patients, families of patients, physicians and other health professionals, and the general public, information on research, prevention, diagnosis, and treatment of heart, blood vessel, lung, and blood diseases, the maintenance of health to reduce the incidence of such diseases, and on the use of blood and blood products and the management of blood resources. In carrying out this section the Director of the Institute shall place special emphasis upon—

"(1) the dissemination of information regarding diet and nutrition, environmental pollutants, exercise, stress, hypertension, cigarette smoking, weight control, and other factors affecting the prevention of arteriosclerosis and other cardiovascular diseases and of pulmonary and blood diseases; and

"(2) the dissemination of information designed to encourage children to adopt healthful habits respecting the risk factors related to the prevention of such diseases.

"NATIONAL HEART, BLOOD VESSEL, LUNG, AND BLOOD DISEASES AND BLOOD RESOURCES PROGRAM

"SEC. 421. (a)(1) The National Heart, Blood Vessel, Lung, and Blood Diseases and Blood Resources Program (hereafter in this subpart referred to as the 'Program') may provide for—

"(A) investigation into the epidemiology, etiology, and prevention of all forms and aspects of heart, blood vessel, lung, and blood diseases, including investigations into the social, en-

vironmental, behavioral, nutritional, biological, and genetic determinants and influences involved in the epidemiology, etiology, and prevention of such diseases;

"(B) studies and research into the basic biological processes and mechanisms involved in the underlying normal and abnormal heart, blood vessel, lung, and blood phenomena;

"(C) research into the development, trial, and evaluation of techniques, drugs, and devices (including computers) used in, and approaches to, the diagnosis, treatment (including the provision of emergency medical services), and prevention of heart, blood vessel, lung, and blood diseases and the rehabilitation of patients suffering from such diseases;

"(D) establishment of programs that will focus and apply scientific and technological efforts involving the biological, physical, and engineering sciences to all facets of heart, blood vessel, lung, and blood diseases with emphasis on the refinement, development, and evaluation of technological devices that will assist, replace, or monitor vital organs and improve instrumentation for detection, diagnosis, and treatment of such diseases;

"(E) establishment of programs for the conduct and direction of field studies, large-scale testing and evaluation, and demonstration of preventive, diagnostic, therapeutic, and rehabilitative approaches to, and emergency medical services for, such diseases;

"(F) studies and research into blood diseases and blood, and into the use of blood for clinical purposes and all aspects of the management of blood resources in the United States, including the collection, preservation, fractionation, and distribution of blood and blood products;

"(G) the education (including continuing education) and training of scientists, clinical investigators, and educators in fields and specialties (including computer sciences) requisite to the conduct of clinical programs respecting heart, blood vessel, lung, and blood diseases and blood resources;

"(H) public and professional education relating to all aspects of such diseases, including the prevention of such diseases, and the use of blood and blood products and the management of blood resources;

"(I) establishment of programs for study and research into heart, blood vessel, lung, and blood diseases of children (including cystic fibrosis, hyaline membrane, hemolytic diseases such as sickle cell anemia and Cooley's anemia, and hemophilic diseases) and for the development and demonstration of diagnostic, treatment, and preventive approaches to such diseases; and

"(J) establishment of programs for study, research, development, demonstrations, and evaluation of emergency medical services for people who become critically ill in connection with heart, blood vessel, lung, or blood diseases.

"(2) The Program shall be coordinated with other national research institutes to the extent that they have responsibilities respecting such diseases and shall give special emphasis to the continued development in the Institute of programs related to the causes of stroke and to effective coordination of such programs with related stroke programs in the National Institute of Neurolog-

ical and Communicative Disorders and Stroke. The Director of the Institute, with the advice of the advisory council for the Institute, shall revise annually the plan for the Program and shall carry out the Program in accordance with such plan.

"(b) In carrying out the Program, the Director of the Institute, under policies established by the Director of NIH—

"(1) may, after approval of the advisory council for the Institute, obtain (in accordance with section 3109 of title 5, United States Code, but without regard to the limitation in such section on the period of service) the services of not more than one hundred experts or consultants who have scientific or professional qualifications;

"(2)(A) may, in consultation with the advisory council for the Institute, acquire and construct, improve, repair, operate, alter, renovate, and maintain, heart, blood vessel, lung, and blood disease and blood resource laboratory, research, training, and other facilities, equipment, and such other real or personal property as the Director determines necessary;

"(B) may, in consultation with the advisory council for the Institute, make grants for construction or renovation of facilities; and

"(C) may, in consultation with the advisory council for the Institute, acquire, without regard to the Act of March 3, 1877 (40 U.S.C. 34), by lease or otherwise, through the Administrator of General Services, buildings or parts of buildings in the District of Columbia or communities located adjacent to the District of Columbia for the use of the Institute for a period not to exceed ten years;

"(3) subject to section 405(b)(2) and without regard to section 3324 of title 31, United States Code, and section 3709 of the Revised Statutes (41 U.S.C. 5), may enter into such contracts, leases, cooperative agreements, or other transactions, as may be necessary in the conduct of the Director's functions, with any public agency, or with any person, firm, association, corporation, or educational institutions; and

"(4) may make grants to public and nonprofit private entities to assist in meeting the cost of the care of patients in hospitals, clinics, and related facilities who are participating in research projects.

"(c) Except as otherwise provided, experts and consultants whose services are obtained under paragraph (1) of subsection (b) shall be paid or reimbursed, in accordance with title 5, United States Code, for their travel to and from their place of service and for other expenses associated with their assignment. Such expenses shall not be allowed in connection with the assignment of an expert or consultant whose services are obtained under such paragraph unless the expert or consultant has agreed in writing to complete the entire period of the assignment or one year of the assignment, whichever is shorter, unless separated or reassigned for reasons which are beyond the control of the expert or consultant and which are acceptable to the Director of the Institute. If the expert or consultant violates the agreement, the money spent by the United States for such expenses is recoverable from the expert or consult-

ant as a debt due the United States. The Secretary may waive in whole or in part a right of recovery under this subsection.

"NATIONAL RESEARCH AND DEMONSTRATION CENTERS FOR HEART, BLOOD VESSEL, LUNG, AND BLOOD DISEASES, SICKLE CELL ANEMIA, AND BLOOD RESOURCES

"SEC. 422. (a)(1) The Director of the Institute may provide, in accordance with subsection (c), for the development of—

"(A) ten centers for basic and clinical research into, training in, and demonstration of, advanced diagnostic, prevention, and treatment methods (including methods of providing emergency medical services) for heart and blood vessel diseases;

"(B) ten centers for basic and clinical research into, training in, and demonstration of, advanced diagnostic, prevention, and treatment methods (including methods of providing emergency medical services) for lung diseases (including bronchitis, emphysema, asthma, cystic fibrosis, and other lung diseases of children); and

"(C) ten centers for basic and clinical research into, training in, and demonstration of, advanced diagnostic, prevention, and treatment methods (including methods of providing emergency medical services) for blood diseases and research into blood, in the use of blood products and in the management of blood resources.

"(2) The centers developed under paragraph (1) shall, in addition to being utilized for research, training, and demonstrations, be utilized for the following prevention programs for cardiovascular, pulmonary, and blood diseases:

"(A) Programs to develop improved methods of detecting individuals with a high risk of developing cardiovascular, pulmonary, and blood diseases.

"(B) Programs to develop improved methods of intervention against those factors which cause individuals to have a high risk of developing such diseases.

"(C) Programs to develop health professions and allied health professions personnel highly skilled in the prevention of such diseases.

"(D) Programs to develop improved methods of providing emergency medical services for persons with such diseases.

"(E) Programs of continuing education for health and allied health professionals in the diagnosis, prevention, and treatment of such diseases and the maintenance of health to reduce the incidence of such diseases and information programs for the public respecting the prevention and early diagnosis and treatment of such diseases and the maintenance of health.

"(3) The research, training, and demonstration activities carried out through any such center may relate to any one or more of the diseases referred to in paragraph (1) of this subsection.

"(b) The Director of the Institute shall provide, in accordance with subsection (c), for the development of ten centers for basic and clinical research into the diagnosis, treatment, and control of sickle cell anemia.

"(c)(1) The Director of the Institute may enter into cooperative agreements with and make grants to public or private nonprofit entities to pay all or part of the cost of planning, establishing, or strengthening, and providing basic operating support for centers for basic and clinical research into, training in, and demonstration of the management of blood resources and advanced diagnostic, prevention, and treatment methods for heart, blood vessel, lung, or blood diseases.

"(2) A cooperative agreement or grant under paragraph (1) shall be entered into in accordance with policies established by the Director of NIH and after consultation with the Institute's advisory council.

"(3) Federal payments made under a cooperative agreement or grant under paragraph (1) may be used for—

"(A) construction (notwithstanding any limitation under section 494);

"(B) staffing and other basic operating costs, including such patient care costs as are required for research;

"(C) training, including training for allied health professionals; and

"(D) demonstration purposes.

"(4) As used in this subsection, the term 'construction' does not include the acquisition of land, and the term 'training' does not include research training for which National Research Service Awards may be provided under section 485.

"(5) Support of a center under paragraph (1) may be for a period of not to exceed five years. Such period may be extended by the Director for additional periods of not more than five years each if the operations of such center have been reviewed by an appropriate scientific review group established by the Director and if such group has recommended to the Director that such period should be extended.

"INTERAGENCY TECHNICAL COMMITTEE

"SEC. 423. (a) The Secretary shall establish an Interagency Technical Committee on Heart, Blood Vessel, Lung and Blood Diseases and Blood Resources which shall be responsible for coordinating those aspects of all Federal health programs and activities relating to heart, blood vessel, lung, and blood diseases and blood resources to assure the adequacy and technical soundness of such programs and activities and to provide for the full communication and exchange of information necessary to maintain adequate coordination of such programs and activities.

"(b) The Director of the Institute shall serve as chairman of the Committee and the Committee shall include representation from all Federal departments and agencies whose programs involve health functions or responsibilities relevant to the functions of the Committee, as determined by the Secretary.

"ASSOCIATE DIRECTOR FOR PREVENTION

"SEC. 424. (a) There shall be in the Institute an Associate Director for Prevention to coordinate and promote the programs in the Institute concerning the prevention of heart, blood vessel, lung,

and blood diseases. The Associate Director shall be appointed by the Director of the Institute from individuals who because of their professional training or experience are experts in public health or preventive medicine.

"(b) The Associate Director for Prevention shall prepare for inclusion in the biennial report made under section 407 a description of the prevention activities of the Institute, including a description of the staff and resources allocated to those activities.

"Subpart 3—National Institute of Diabetes and Digestive and Kidney Diseases

"PURPOSE OF THE INSTITUTE

"SEC. 426. The general purpose of the National Institute of Diabetes and Digestive and Kidney Diseases (hereafter in this subpart referred to as the 'Institute') is the conduct and support of research, training, health information dissemination, and other programs with respect to diabetes mellitus and endocrine and metabolic diseases, digestive diseases and nutritional disorders, and kidney, urologic, and hematologic diseases.

"DATA SYSTEMS AND INFORMATION CLEARINGHOUSES

"SEC. 427. (a) The Director of the Institute shall (1) establish the National Diabetes Data System for the collection, storage, analysis, retrieval, and dissemination of data derived from patient populations with diabetes, including, where possible, data involving general populations for the purpose of detection of individuals with a risk of developing diabetes, and (2) establish the National Diabetes Information Clearinghouse to facilitate and enhance knowledge and understanding of diabetes on the part of health professionals, patients, and the public through the effective dissemination of information.

"(b) The Director of the Institute shall (1) establish the National Digestive Diseases Data System for the collection, storage, analysis, retrieval, and dissemination of data derived from patient populations with digestive diseases, including, where possible, data involving general populations for the purpose of detection of individuals with a risk of developing digestive diseases, and (2) establish the National Digestive Diseases Information Clearinghouse to facilitate and enhance knowledge and understanding of digestive diseases on the part of health professionals, patients, and the public through the effective dissemination of information.

"(c) The Director of the Institute shall (1) establish the National Kidney and Urologic Diseases Data System for the collection, storage, analysis, retrieval, and dissemination of data derived from patient populations with kidney and urologic diseases, including, where possible, data involving general populations for the purpose of detection of individuals with a risk of developing kidney and urologic diseases and (2) establish the National Kidney and Urologic Diseases Information Clearinghouse to facilitate and enhance knowledge and understanding of kidney and urologic diseases on the part of health professionals, patients, and the public through the effective dissemination of information.

"DIVISION DIRECTORS FOR DIABETES, ENDOCRINOLOGY, AND METABOLIC DISEASES, DIGESTIVE DISEASEA AND NUTRITION, AND KIDNEY, UROLOGIC, AND HEMATOLOGIC DISEASES

"SEC. 428. (a)(1) In the Institute there shall be a Division Director for Diabetes, Endocrinology, and Metabolic Diseases, a Division Director for Digestive Diseases and Nutrition, and a Division Director for Kidney, Urologic, and Hematologic Diseases. Such Division Directors, under the supervision of the Director of the Institute, shall be responsible for—

"(A) developing a coordinated plan (including recommendations for expenditures) for each of the national research institutes within the National Institutes of Health with respect to research and training concerning diabetes, endocrine and metabolic diseases, digestive diseases and nutrition, and kidney, urologic, and hematologic diseases;

"(B) assessing the adequacy of management approaches for the activities within such institutes concerning such diseases and nutrition and developing improved approaches if needed;

"(C) monitoring and reviewing expenditures by such institutes concerning such diseases and nutrition; and

"(D) identifying research opportunities concerning such diseases and nutrition and recommending ways to utilize such opportunities.

"(2) The Director of the Institute shall transmit to the Director of NIH the plans, recommendations, and reviews of the Division Directors under subparagraphs (A) through (D) of paragraph (1) and such comments and recommendations as the Director of the Institute determines appropriate.

"(b) The Director of the Institute, acting through the Division Director for Diabetes, Endocrinology, and Metabolic Diseases, the Division Director for Digestive Diseases and Nutrition, and the Division Director for Kidney, Urologic, and Hematologic Diseases shall—

"(1) carry out programs of support for research and training (other than training for which National Research Service Awards may be made under section 485) in the diagnosis, prevention, and treatment of diabetes mellitus and endocrine and metabolic diseases, digestive diseases and nutritional disorders, and kidney, urologic, and hematologic diseases, including support for training in medical schools, graduate clinical training, graduate training in epidemiology, epidemiology studies, clinical trials, and interdisciplinary research programs; and

"(2) establish programs of evaluation, planning, and dissemination of knowledge related to such research and training.

"INTERAGENCY COORDINATING COMMITTEES

"SEC. 429. (a) For the purpose of—

"(1) better coordination of the research activities of all the national research institutes relating to diabetes mellitus, digestive diseases, and kidney, urologic, and hematologic diseases; and

"(2) coordinating those aspects of all Federal health programs and activities relating to such diseases to assure the

adequacy and technical soundness of such programs and activities and to provide for the full communication and exchange of information necessary to maintain adequate coordination of such programs and activities;

the Secretary shall establish a Diabetes Mellitus Interagency Coordinating Committee, a Digestive Diseases Interagency Coordinating Committee, and a Kidney, Urologic, and Hematologic Diseases Coordinating Committee (hereafter in this section individually referred to as a 'Committee').

"(b) Each Committee shall be composed of the Directors of each of the national research institutes and divisions involved in research with respect to the diseases for which the committee is established, the Division Director of the Institute for the diseases for which the committee is established, the Chief Medical Director of the Veterans' Administration, and the Assistant Secretary of Defense for Health Affairs (or the designees of such officers), and shall include representation from all other Federal departments and agencies whose programs involve health functions or responsibilities relevant to such diseases, as determined by the Secretary. Each Committee shall be chaired by the Director of NIH (or the designee of such Director). Each Committee shall meet at the call of the chairman, but not less often than four times a year.

"(c) Each Committee shall prepare an annual report for—

"(1) the Secretary;

"(2) the Director of NIH; and

"(3) the Advisory Board established under section 430 for the diseases for which the Committee was established,

detailing the work of the Committee in carrying out paragraphs (1) and (2) of subsection (a) in the fiscal year for which the report was prepared. Such report shall be submitted not later than 120 days after the end of each fiscal year.

"ADVISORY BOARDS

"SEC. 430. (a) The Secretary shall establish in the Institute the National Diabetes Advisory Board, the National Digestive Diseases Advisory Board, and the National Kidney and Urologic Diseases Advisory Board (hereafter in this section individually referred to as an 'Advisory Board').

"(b) Each Advisory Board shall be composed of eighteen appointed members and nonvoting ex officio members as follows:

"(1) The Secretary shall appoint—

"(A) twelve members from individuals who are scientists, physicians, and other health professionals, who are not officers or employees of the United States, and who represent the specialties and disciplines relevant to the diseases with respect to which the Advisory Board is established; and

"(B) six members from the general public who are knowledgeable with respect to such diseases, including at least one member who is a person who has such a disease and one member who is a parent of a person who has such a disease.

Of the appointed members, at least five shall by virtue of training or experience be knowledgeable in the fields of health education, nursing, data systems, public information, and community program development.

"(2)(A) The following shall be ex officio members of each Advisory Board:

"(i) The Assistant Secretary for Health, the Director of NIH, the Director of the National Institute of Diabetes and Digestive and Kidney Diseases, the Director of the Centers for Disease Control, the Chief Medical Director of the Veterans' Administration, the Assistant Secretary of Defense for Health Affairs, and the Division Director of the National Institute of Diabetes and Digestive and Kidney Diseases for the diseases for which the Board is established (or the designees of such officers).

"(ii) Such other officers and employees of the United States as the Secretary determines necessary for the Advisory Board to carry out its functions.

"(B) In the case of the National Diabetes Advisory Board, the following shall also be ex officio members: The Director of the National Heart, Lung, and Blood Institute, the Director of the National Eye Institute, the Director of the National Institute of Child Health and Human Development, and the Administrator of the Health Resources and Services Administration (or the designees of such officers).

"(c) Members of an Advisory Board who are officers or employees of the Federal Government shall serve as members of the Advisory Board without compensation in addition to that received in their regular public employment. Other members of the Board shall receive compensation at rates not to exceed the daily equivalent of the annual rate in effect for grade GS–18 of the General Schedule for each day (including traveltime) they are engaged in the performance of their duties as members of the Board.

"(d) The term of office of an appointed member of an Advisory Board is four years, except that no term of office may extend beyond the expiration of the Advisory Board. Any member appointed to fill a vacancy for an unexpired term shall be appointed for the remainder of such term. A member may serve after the expiration of the member's term until a successor has taken office. If a vacancy occurs in an Advisory Board, the Secretary shall make an appointment to fill the vacancy not later than 90 days from the date the vacancy occurred.

"(e) The members of each Advisory Board shall select a chairman from among the appointed members.

"(f) The Secretary shall, after consultation with and consideration of the recommendations of an Advisory Board, provide the Advisory Board with an executive director and one other professional staff member. In addition, the Secretary shall, after consultation with and consideration of the recommendations of the Advisory Board, provide the Advisory Board with such additional professional staff members, such clerical staff members, and (through contracts or other arrangements) such administrative support services and facilities, such information, and such services of consult-

ants, as the Secretary determines are necessary for the Advisory Board to carry out its functions.

"(g) Each Advisory Board shall meet at the call of the chairman or upon request of the Director of the Institute, but not less often than four times a year.

"(h) The National Diabetes Advisory Board and the National Digestive Diseases Advisory Board shall—

"(1) review and evaluate the implementation of the plan (referred to in section 433) respecting the diseases with respect to which the Advisory Board was established and periodically update the plan to ensure its continuing relevance;

"(2) for the purpose of assuring the most effective use and organization of resources respecting such diseases, advise and make recommendations to the Congress, the Secretary, the Director of NIH, the Director of the Institute, and the heads of other appropriate Federal agencies for the implementation and revision of such plan; and

"(3) maintain liaison with other advisory bodies related to Federal agencies involved in the implementation of such plan, the coordinating committee for such diseases, and with key non-Federal entities involved in activities affecting the control of such diseases.

"(i) In carrying out its functions, each Advisory Board may establish subcommittees, convene workshops and conferences, and collect data. Such subcommittees may be composed of Advisory Board members and nonmember consultants with expertise in the particular area addressed by such subcommittees. The subcommittees may hold such meetings as are necessary to enable them to carry out their activities.

"(j) Each Advisory Board shall prepare an annual report for the Secretary which—

"(1) describes the Advisory Board's activities in the fiscal year for which the report is made;

"(2) describes and evaluates the progress made in such fiscal year in research, treatment, education, and training with respect to the diseases with respect to which the Advisory Board was established;

"(3) summarizes and analyzes expenditures made by the Federal Government for activities respecting such diseases in such fiscal year; and

"(4) contains the Advisory Board's recommendations (if any) for changes in the plan referred to in section 433.

"(k) Each Advisory Board shall expire on September 30, 1988.

"(l) The National Diabetes Advisory Board and the National Digestive Diseases Advisory Board in existence on the effective date of the Health Research Extension Act of 1985 shall terminate upon the appointment of a successor Board under subsection (a). The Secretary shall make appointments to the Advisory Boards established under subsection (a) before the expiration of 90 days after such effective date. The members of the Boards in existence on such date may be appointed, in accordance with subsections (b) and (d), to the Boards established under subsection (a) for diabetes and digestive diseases, except that at least one-half of the members of the National Diabetes Advisory Board in existence on the effective

date of the Health Research Extension Act of 1985 shall be appointed to the National Diabetes Advisory Board first established under subsection (a).

"RESEARCH AND TRAINING CENTERS

"Sec. 431. (a)(1) Consistent with applicable recommendations of the National Commission on Diabetes, the Director of the Institute shall provide for the development or substantial expansion of centers for research and training in diabetes mellitus and related endocrine and metabolic diseases. Each center developed or expanded under this subsection shall—

"(A) utilize the facilities of a single institution, or be formed from a consortium of cooperating institutions, meeting such research and training qualifications as may be prescribed by the Secretary; and

"(B) conduct—

"(i) research in the diagnosis and treatment of diabetes mellitus and related endocrine and metabolic diseases and the complications resulting from such diseases;

"(ii) training programs for physicians and allied health personnel in current methods of diagnosis and treatment of such diseases and complications, and in research in diabetes; and

"(iii) information programs for physicians and allied health personnel who provide primary care for patients with such diseases or complications.

"(2) A center may use funds provided under this subsection to provide stipends for nurses and allied health professionals enrolled in research training programs described in paragraph (1)(B)(ii).

"(b) Consistent with applicable recommendations of the National Digestive Diseases Advisory Board, the Director shall provide for the development or substantial expansion of centers for research in digestive diseases and related functional, congenital, metabolic disorders, and normal development of the digestive tract. Each center developed or expanded under this subsection—

"(1) shall utilize the facilities of a single institution, or be formed from a consortium of cooperating institutions, meeting such research qualifications as may be prescribed by the Secretary;

"(2) shall develop and conduct basic and clinical research into the cause, diagnosis, early detection, prevention, control, and treatment of digestive diseases and nutritional disorders and related functional, congenital, or metabolic complications resulting from such diseases or disorders;

"(3) shall encourage research into and programs for—

"(A) providing information for patients with such diseases, disorders, and complications and the families of such patients, physicians and others who care for such patients, and the general public;

"(B) model programs for cost effective and preventive patient care; and

"(C) training physicians and scientists in research on such diseases, disorders, and complications; and

"(4) may perform research and participate in epidemiological studies and data collection relevant to digestive diseases and disorders in order to disseminate such research, studies, and data to the health care profession and to the public.

"(c) The Director shall provide for the development, establishment, or substantial expansion of centers for research in kidney and urologic diseases. Each center developed, established, or expanded under this subsection—

"(1) shall utilize the facilities of a single institution, or be formed from a consortium of cooperating institutions, meeting such research qualifications as may be prescribed by the Secretary;

"(2) shall develop and conduct basic and clinical research into the cause, diagnosis, early detection, prevention, control, and treatment of kidney and urologic diseases;

"(3) shall encourage research into and programs for—

"(A) providing information for patients with such diseases and the families of such patients, physicians and others who care for such patients, and the general public;

"(B) model programs for cost effective and preventive patient care; and

"(C) training physicians and scientists in research on such diseases; and

"(4) may perform research and participate in epidemiological studies and data collection relevant to kidney and urologic diseases in order to disseminate such research, studies, and data to the health care profession and to the public.

"(d) Insofar as practicable, centers developed, established, or expanded under this section should be geographically dispersed throughout the United States and in environments with proven research capabilities. Support of a center under this section may be for a period of not to exceed five years and such period may be extended by the Director of the Institute for additional periods of not more than five years each if the operations of such center have been reviewed by an appropriate scientific review group established by the Director and if such group has recommended to the Director that such period should be extended.

"ADVISORY COUNCIL SUBCOMMITTEES

"SEC. 432. There are established within the advisory council for the Institute appointed under section 406 a subcommittee on diabetes and endocrine and metabolic diseases, a subcommittee on digestive diseases and nutrition, and a subcommittee on kidney, urologic, and hematologic diseases. The subcommittees shall be composed of members of the advisory council who are outstanding in the diagnosis, prevention, and treatment of the diseases for which the subcommittees are established and members of the advisory council who are leaders in the fields of education and public affairs. The subcommittees are authorized to review applications made to the Director of the Institute for grants for research and training projects relating to the diagnosis, prevention, and treatment of the diseases for which the subcommittees are established and shall recommend to the advisory council those applications and contracts

that the subcommittees determine will best carry out the purposes of the Institute. The subcommittees shall also review and evaluate the diabetes and endocrine and metabolic diseases, digestive diseases and nutrition, and kidney, urologic, and hematologic diseases programs of the Institute and recommend to the advisory council such changes in the administration of such programs as the subcommittees determine are necessary.

"BIENNIAL REPORT

"SEC. 433. The Director of the Institute shall prepare for inclusion in the biennial report made under section 407 a description of the Institute's activities—

"(1) under the current diabetes plan under the National Diabetes Mellitus Research and Education Act; and

"(2) under the current digestive diseases plan formulated under the Arthritis, Diabetes, and Digestive Diseases Amendments of 1976.

The description submitted by the Director shall include an evaluation of the activities of the centers supported under section 431.

"Subpart 4—National Institute of Arthritis and Musculoskeletal and Skin Diseases

"PURPOSE OF THE INSTITUTE

"SEC. 435. The general purpose of the National Institute of Arthritis and Musculoskeletal and Skin Diseases (hereafter in this subpart referred to as the 'Institute') is the conduct and support of research and training, the dissemination of health information, and other programs with respect to arthritis and musculoskeletal and skin diseases, including sports-related disorders.

"NATIONAL ARTHRITIS AND MUSCULOSKELETAL DISEASES PROGRAM

"SEC. 436. (a) The Director of the Institute, with the advice of the Institute's advisory council, shall prepare and transmit to the Director of NIH a plan for a national arthritis and musculoskeletal diseases program to expand, intensify, and coordinate the activities of the Institute respecting arthritis and musculoskeletal diseases. The plan shall include such comments and recommendations as the Director of the Institutes determines appropriate. The Director of the Institute shall periodically review and revise such plan and shall transmit any revisions of such plan to the Director of NIH.

"(b) Activities under the national arthritis and musculoskeletal diseases program shall be coordinated with the other national research institutes to the extent that such institutes have responsibilities respecting arthritis and musculoskeletal diseases, and shall, at least, provide for—

"(1) investigation into the epidemiology, etiology, and prevention of all forms of arthritis and musculoskeletal diseases, including sports-related disorders, primarily through the support of basic research in such areas as immunology, genetics, biochemistry, microbiology, physiology, bioengineering, and any other scientific discipline which can contribute important

knowledge to the treatment and understanding of arthritis and musculoskeletal diseases;

"(2) research into the development, trial, and evaluation of techniques, drugs, and devices used in the diagnosis, treatment, including medical rehabilitation and prevention of arthritis and musculoskeletal diseases;

"(3) research on the refinement, development, and evaluation of technological devices that will replace or be a substitute for damaged bone, muscle, and joints and other supporting structures; and

"(4) the establishment of mechanisms to monitor the causes of athletic injuries and identify ways of preventing such injuries on scholastic athletic fields.

"(c) The Director of the Institute shall carry out the national arthritis and musculoskeletal diseases program in accordance with the plan prepared under subsection (a) and any revisions of such plan made under such subsection.

"RESEARCH AND TRAINING

"SEC. 437. The Director of the Institute shall—

"(1) carry out programs of support for research and training (other than training for which National Research Service Awards may be made under section 485) in the diagnosis, prevention, and treatment of arthritis and musculoskeletal and skin diseases, including support for training in medical schools, graduate clinical training, graduate training in epidemiology, epidemiology studies, clinical trials, and interdisciplinary research programs; and

"(2) establish programs of evaluation, planning, and dissemination of knowledge related to such research and training.

"DATA SYSTEM AND INFORMATION CLEARINGHOUSE

"SEC. 438. (a) The Director of the Institute shall establish the National Arthritis and Musculoskeletal and Skin Diseases Data System for the collection, storage, analysis, retrieval, and dissemination of data derived from patient populations with arthritis and musculoskeletal and skin diseases, including where possible, data involving general populations for the purpose of detection of individuals with a risk of developing arthritis and musculoskeletal and skin diseases.

"(b) The Director of the Institute shall establish the National Arthritis and Musculoskeletal and Skin Diseases Information Clearinghouse to facilitate and enhance, through the effective dissemination of information, knowledge and understanding of arthritis and musculoskeletal and skin diseases by health professionals, patients, and the public.

"INTERAGENCY COORDINATING COMMITTEES

"SEC. 439. (a) For the purpose of—

"(1) better coordination of the research activities of all the national research institutes relating to arthritis, musculoskeletal diseases, and skin diseases, including sports-related disorders; and

"(2) coordinating the aspects of all Federal health programs and activities relating to arthritis, musculoskeletal diseases, and skin diseases in order to assure the adequacy and technical soundness of such programs and activities and in order to provide for the full communication and exchange of information necessary to maintain adequate coordination of such programs and activities,

the Secretary shall establish an Arthritis and Musculoskeletal Diseases Interagency Coordinating Committee and a Skin Diseases Interagency Coordinating Committee (hereafter in this section individually referred to as a 'Committee').

"(b) Each Committee shall be composed of the Directors of each of the national research institutes and divisions involved in research regarding the diseases with respect to which the Committee is established, the Chief Medical Director of the Veterans' Administration, and the Assistant Secretary of Defense for Health Affairs (or the designees of such officers), and representatives of all other Federal departments and agencies (as determined by the Secretary) whose programs involve health functions or responsibilities relevant to arthritis and musculoskeletal diseases or skin diseases, as the case may be. Each Committee shall be chaired by the Director of NIH (or the designee of the Director). Each Committee shall meet at the call of the Chairman, but not less often than four times a year.

"(c) Not later than 120 days after the end of each fiscal year, each Committee shall prepare and transmit to the Secretary, the Director of NIH, the Director of the Institute, and the advisory council for the Institute a report detailing the activities of the Committee in such fiscal year in carrying out paragraphs (1) and (2) of subsection (a).

"ARTHRITIS AND MUSCULOSKELETAL DISEASES DEMONSTRATION PROJECTS

"Sec. 440. (a) The Director of the Institute may make grants to public and private nonprofit entities to establish and support projects for the development and demonstration of methods for screening, detection, and referral for treatment of arthritis and musculoskeletal diseases and for the dissemination of information on such methods to the health and allied health professions. Activities under such projects shall be coordinated with Federal, State, local, and regional health agencies, centers assisted under section 441, and the data system established under subsection (c).

"(b) Projects supported under this section shall include—

"(1) programs which emphasize the development and demonstration of new and improved methods of screening and early detection, referral for treatment, and diagnosis of individuals with a risk of developing arthritis and musculoskeletal diseases;

"(2) programs which emphasize the development and demonstration of new and improved methods for patient referral from local hospitals and physicians to appropriate centers for early diagnosis and treatment;

"(3) programs which emphasize the development and demonstration of new and improved means of standardizing patient data and recordkeeping;

"(4) programs which emphasize the development and demonstration of new and improved methods of dissemination of knowledge about the programs, methods, and means referred to in paragraphs (1), (2), and (3) of this subsection to health and allied health professionals;

"(5) programs which emphasize the development and demonstration of new and improved methods for the dissemination to the general public of information—

"(A) on the importance of early detection of arthritis and musculoskeletal diseases, of seeking prompt treatment, and of following an appropriate regimen; and

"(B) to discourage the promotion and use of unapproved and ineffective diagnostic, preventive treatment, and control methods for arthritis and unapproved and ineffective drugs and devices for arthritis and musculoskeletal diseases; and

"(6) projects for investigation into the epidemiology of all forms and aspects of arthritis and musculoskeletal diseases, including investigations into the social, environmental, behavioral, nutritional, and genetic determinants and influences involved in the epidemiology of arthritis and musculoskeletal diseases.

"(c) The Director shall provide for the standardization of patient data and recordkeeping for the collection, storage, analysis, retrieval, and dissemination of such data in cooperation with projects assisted under this section, centers assisted under section 441, and other persons engaged in arthritis and musculoskeletal disease programs.

"MULTIPURPOSE ARTHRITIS AND MUSCULOSKELETAL DISEASES CENTERS

"SEC. 441. (a) The Director of the Institute shall, after consultation with the advisory council for the Institute, provide for the development, modernization, and operation (including staffing and other operating costs such as the costs of patient care required for research) of new and existing centers for arthritis and musculoskeletal diseases. For purposes of this section, the term 'modernization' means the alteration, remodeling, improvement, expansion, and repair of existing buildings and the provision of equipment for such buildings to the extent necessary to make them suitable for use as centers described in the preceding sentence.

"(b) Each center assisted under this section shall—

"(1)(A) use the facilities of a single institution or a consortium of cooperating institutions, and (B) meet such qualifications as may be prescribed by the Secretary; and

"(2) conduct—

"(A) basic and clinical research into the cause, diagnosis, early detection, prevention, control, and treatment of arthritis and musculoskeletal diseases and complications resulting from arthritis and musculoskeletal diseases, includ-

ing research into implantable biomaterials and biomechanical and other orthopedic procedures;

"(B) training programs for physicians, scientists, and other health and allied health professionals;

"(C) information and continuing education programs for physicians and other health and allied health professionals who provide care for patients with arthritis and musculoskeletal diseases; and

"(D) programs for the dissemination to the general public of information—

"(i) on the importance of early detection of arthritis and musculoskeletal diseases, of seeking prompt treatment, and of following an appropriate regimen; and

"(ii) to discourage the promotion and use of unapproved and ineffective diagnostic, preventive, treatment, and control methods and unapproved and ineffective drugs and devices.

A center may use funds provided under subsection (a) to provide stipends for health professionals enrolled in training programs described in paragraph (2)(B).

"(c) Each center assisted under this section may conduct programs to—

"(1) establish the effectiveness of new and improved methods of detection, referral, and diagnosis of individuals with a risk of developing arthritis and musculoskeletal diseases;

"(2) disseminate the results of research, screening, and other activities, and develop means of standardizing patient data and recordkeeping; and

"(3) develop community consultative services to facilitate the referral of patients to centers for treatment.

"(d) The Director of the Institute shall, insofar as practicable, provide for an equitable geographical distribution of centers assisted under this section. The Director shall give appropriate consideration to the need for centers especially suited to meeting the needs of children affected by arthritis and musculoskeletal diseases.

"(e) Support of a center under this section may be for a period of not to exceed five years. Such period may be extended by the Director of the Institute for one or more additional periods of not more than five years if the operations of such center have been reviewed by an appropriate scientific review group established by the Director and if such group has recommended to the Director that such period should be extended.

ADVISORY BOARD

"SEC. 442. (a) The Secretary shall establish in the Institute the National Arthritis Advisory Board (hereafter in this section referred to as the 'Advisory Board').

"(b) The Advisory Board shall be composed of eighteen appointed members and nonvoting, ex officio members, as follows:

"(1) The Secretary shall appoint—

"(A) twelve members from individuals who are scientists, physicians, and other health professionals, who are not officers or employees of the United States, and who

represent the specialties and disciplines relevant to arthritis, musculoskeletal diseases, and skin diseases; and

"(B) six members from the general public who are knowledgeable with respect to such diseases, including at least one member who is a person who has such a disease and one member who is a parent of a person who has such a disease.

Of the appointed members, at least five shall by virtue of training or experience be knowledgeable in health education, nursing, data systems, public information, or community program development.

"(2) The following shall be ex officio members of the Advisory Board: The Assistant Secretary for Health, the Director of NIH, the Director of the National Institute of Arthritis and Musculoskeletal and Skin Diseases, the Director of the Centers for Disease Control, the Chief Medical Director of the Veterans' Administration, and the Assistant Secretary of Defense for Health Affairs (or the designees of such officers), and such other officers and employees of the United States as the Secretary determines necessary for the Advisory Board to carry out its functions.

"(c) Members of the Advisory Board who are officers or employees of the Federal Government shall serve as members of the Advisory Board without compensation in addition to that received in their regular public employment. Other members of the Advisory Board shall receive compensation at rates not to exceed the daily equivalent of the annual rate in effect for grade GS–18 of the General Schedule for each day (including traveltime) they are engaged in the performance of their duties as members of the Advisory Board.

"(d) The term of office of an appointed member of the Advisory Board is four years. Any member appointed to fill a vacancy for an unexpired term shall be appointed for the remainder of such term. A member may serve after the expiration of the member's term until a successor has taken office. If a vacancy occurs in the Advisory Board, the Secretary shall make an appointment to fill the vacancy not later than 90 days after the date the vacancy occurred.

"(e) The members of the Advisory Board shall select a chairman from among the appointed members.

"(f) The Secretary shall, after consultation with and consideration of the recommendations of the Advisory Board, provide the Advisory Board with an executive director and one other professional staff member. In addition, the Secretary shall, after consultation with and consideration of the recommendations of the Advisory Board, provide the Advisory Board with such additional professional staff members, such clerical staff members, and (through contracts or other arrangements) with such administrative support services and facilities, such information, and such services of consultants, as the Secretary determines are necessary for the Advisory Board to carry out its functions.

"(g) The Advisory Board shall meet at the call of the chairman or upon request of the Director of the Institute, but not less often than four times a year.

"(h) The Advisory Board shall—

"(1) review and evaluate the implementation of the plan prepared under section 436(a) and periodically update the plan to ensure its continuing relevance;

"(2) for the purpose of assuring the most effective use and organization of resources respecting arthritis, musculoskeletal diseases and skin diseases, advise and make recommendations to the Congress, the Secretary, the Director of NIH, the Director of the Institute, and the heads of other appropriate Federal agencies for the implementation and revision of such plan; and

"(3) maintain liaison with other advisory bodies for Federal agencies involved in the implementation of such plan, the interagency coordinating committees for such diseases established under section 439, and with key non-Federal entities involved in activities affecting the control of such diseases.

"(i) In carrying out its functions, the Advisory Board may establish subcommittees, convene workshops and conferences, and collect data. Such subcommittees may be composed of Advisory Board members and nonmember consultants with expertise in the particular area addressed by such subcommittees. The subcommittees may hold such meetings as are necessary to enable them to carry out their activities.

"(j) The Advisory Board shall prepare an annual report for the Secretary which—

"(1) describes the Advisory Board's activities in the fiscal year for which the report is made;

"(2) describes and evaluates the progress made in such fiscal year in research, treatment, education, and training with respect to arthritis, musculoskeletal diseases, and skin diseases;

"(3) summarizes and analyzes expenditures made by the Federal Government for activities respecting such diseases in such fiscal year for which the report is made; and

"(4) contains the Advisory Board's recommendations (if any) for changes in the plan prepared under section 436(a).

"(k) The National Arthritis Advisory Board in existence on the effective date of the Health Research Extension Act of 1985 shall terminate upon the appointment of a successor Board under subsection (a). The Secretary shall make appointments to the Advisory Board established under subsection (a) before the expiration of 90 days after such effective date. The member of the Board in existence on such date may be appointed, in accordance with subsections (b) and (d), to the Advisory Board established under subsection (a).

"Subpart 5—National Institute on Aging

"PURPOSE OF THE INSTITUTE

"SEC. 443. The general purpose of the National Institute on Aging (hereafter in this subpart referred to as the 'Institute') is the conduct and support of biomedical, social, and behavioral research, training, health information dissemination, and other programs with respect to the aging process and the diseases and other special problems and needs of the aged.

"SPECIAL FUNCTIONS

"SEC. 444. (a) In carrying out the training responsibilities under this Act or any other Act for health and allied health professions personnel, the Secretary shall take appropriate steps to insure the education and training of adequate numbers of allied health, nursing, and paramedical personnel in the field of health care for the aged.

"(b) The Director of the Institute shall conduct scientific studies to measure the impact on the biological, medical, social, and psychological aspects of aging of programs and activities assisted or conducted by the Department of Health and Human Services.

"(c) The Director of the Institute shall carry out public information and education programs designed to disseminate as widely as possible the findings of research sponsored by the Institute, other relevant aging research and studies, and other information about the process of aging which may assist elderly and near-elderly persons in dealing with, and all Americans in understanding, the problems and processes associated with growing older.

"(d) The Director of the Institute shall make grants to public and private nonprofit institutions to conduct research relating to Alzheimer's Disease.

"ALZHEIMER'S DISEASE CENTERS

"SEC. 445. (a)(1) The Director of the Institute may enter into cooperative agreements with and make grants to public or private nonprofit entities to pay all or part of the cost of planning, establishing, or strengthening, and providing basic operating support for centers for basic and clinical research into, training in, and demonstration of advanced diagnostic, prevention, and treatment methods for Alzheimer's Disease.

"(2) A cooperative agreement or grant under paragraph (1) shall be entered into in accordance with policies established by the Director of NIH and after consultation with the Institute's advisory council.

"(b)(1) Federal payments made under a cooperative agreement or grant under subsection (a) may be used for—

"(A) construction (notwithstanding any limitation under section 494);

"(B) staffing and other basic operating costs, including such patient care costs as are required for research;

"(C) training, including training for allied health professionals; and

"(D) demonstration purposes.

"(2) As used in this subsection, the term 'construction' does not include the acquisition of land, and the term 'training' does not include research training for which National Research Service Awards may be provided under section 485.

"(c) Support of a center under subsection (a) may be for a period of not to exceed five years. Such period may be extended by the Director for additional periods of not more than five years each if the operations of such center have been reviewed by an appropriate scientific review group established by the Director and if such

group has recommended to the Director that such period should be extended.

"Subpart 6—National Institute of Allergy and Infectious Diseases

"PURPOSE OF THE INSTITUTE

"SEC. 446. The general purpose of the National Institute of Allergy and Infectious Diseases is the conduct and support of research, training, health information dissemination, and other programs with respect to allergic and immunologic diseases and disorders and infectious diseases.

"Subpart 7—National Institute of Child Health and Human Development

"PURPOSE OF THE INSTITUTE

"SEC. 448. The general purpose of the National Institute of Child Health and Human Development (hereafter in this subpart referred to as the 'Institute') is the conduct and support of research, training, health information dissemination, and other programs with respect to maternal health, child health, mental retardation, human growth and development, including prenatal development, and special health problems and requirements of mothers and children.

"SUDDEN INFANT DEATH SYNDROME

"SEC. 449. The Director of the Institute shall conduct and support research which specifically relates to sudden infant death syndrome.

"MENTAL RETARDATION RESEARCH

"SEC. 450. The Director of the Institute shall conduct and support research and related activities with respect to the causes, prevention, and treatment of mental retardation.

"ASSOCIATE DIRECTOR FOR PREVENTION

"SEC. 451. (a) There shall be in the Institute an Associate Director for Prevention to coordinate and promote the programs in the Institute concerning the prevention of health problems of mothers and children. The Associate Director shall be appointed by the Director of the Institute from individuals who because of their professional training or experience are experts in public health or preventive medicine.

"(b) The Associate Director for Prevention shall prepare for inclusion in the biennial report made under section 407 a description of the prevention activities of the Institute, including a description of the staff and resources allocated to those activities.

"Subpart 8—National Institute of Dental Research

"PURPOSE OF THE INSTITUTE

"SEC. 453. The general purpose of the National Institute of Dental Research is the conduct and support of research, training,

health information dissemination, and other programs with respect to the cause, prevention, and methods of diagnosis and treatment of dental and oral diseases and conditions.

"Subpart 9—National Eye Institute

"PURPOSE OF THE INSTITUTE

"SEC. 455. The general purpose of the National Eye Institute (hereafter in this subpart referred to as the 'Institute') is the conduct and support of research, training, health information dissemination, and other programs with respect to blinding eye diseases, visual disorders, mechanisms of visual function, preservation of sight, and the special health problems and requirements of the blind. The Director of the Institute may carry out a program of grants for public and private nonprofit vision research facilities.

"Subpart 10—National Institute of Neurological and Communicative Disorders and Stroke

"PURPOSE OF THE INSTITUTE

"SEC. 457. The general purpose of the National Institute of Neurological and Communicative Disorders and Stroke (hereafter in this subpart referred to as the 'Institute') is the conduct and support of research, training, health information dissemination, and other programs with respect to neurological disease and disorder, stroke, and disorders of human communication.

"SPINAL CORD REGENERATION RESEARCH

"SEC. 458. The Director of the Institute shall conduct and support research into spinal cord regeneration.

"BIOENGINEERING RESEARCH

"SEC. 459. The Director of the Institute shall make grants or enter into contracts for research on the means to overcome paralysis of the extremities through electrical stimulation and the use of computers.

"Subpart 11—National Institute of General Medical Sciences

"PURPOSE OF THE INSTITUTE

"SEC. 461. The general purpose of the National Institute of General Medical Sciences is the conduct and support of research, training, and, as appropriate, health information dissemination, and other programs with respect to general or basic medical sciences and related natural or behavioral sciences which have significance for two or more other national research institutes or are outside the general area of responsibility of any other national research institute.

"Subpart 12—National Institute of Environmental Health Sciences

"PURPOSE OF THE INSTITUTE

"SEC. 463. The general purpose of the National Institute of Environmental Health Sciences is the conduct and support of research, training, health information dissemination, and other programs with respect to factors in the environment that affect human health, directly or indirectly.

"PART D—NATIONAL LIBRARY OF MEDICINE

"Subpart 1—General Provisions

"PURPOSE AND ESTABLISHMENT OF THE LIBRARY

"SEC. 467. In order to assist the advancement of medical and related sciences, and to aid the dissemination and exchange of scientific and other information important to the progress of medicine and to the public health, there is established the National Library of Medicine (hereafter in this part referred to as the 'Library').

"FUNCTIONS OF THE LIBRARY

"SEC. 468. (a) The Secretary, through the Library and subject to subsection (c), shall—

"(1) acquire and preserve books, periodicals, prints, films, recordings, and other library materials pertinent to medicine;

"(2) organize the materials specified in paragraph (1) by appropriate cataloging, indexing, and bibliographical listings;

"(3) publish and disseminate the catalogs, indexes, and bibliographies referred to in paragraph (2);

"(4) make available, through loans, photographic or other copying procedures, or otherwise, such materials in the Library as the Secretary determines appropriate;

"(5) provide reference and research assistance; and

"(6) engage in such other activities as the Secretary determines appropriate and as the Library's resources permit.

"(b) The Secretary may exchange, destroy, or otherwise dispose of any books, periodicals, films, and other library materials not needed for the permanent use of the Library.

"(c)(1) The Secretary may, after obtaining the advice and recommendations of the Board of Regents, prescribe rules under which the Library will—

"(A) provide copies of its publications or materials,

"(B) will make available its facilities for research, or

"(C) will make available its bibliographic, reference, or other services,

to public and private entities and individuals.

"(2) Rules prescribed under paragraph (1) may provide for making available such publications, materials, facilities, or services—

"(A) without charge as a public service,

"(B) upon a loan, exchange, or charge basis, or

"(C) in appropriate circumstances, under contract arrangements made with a public or other nonprofit entity.

"(d) Whenever the Secretary, with the advice of the Board of Regents, determines that—

"(1) in any geographic area of the United States there is no regional medical library adequate to serve such area;

"(2) under criteria prescribed for the administration of section 478, there is a need for a regional medical library to serve such area; and

"(3) because there is no medical library located in such area which, with financial assistance under section 478, can feasibly be developed into a regional medical library adequate to serve such area,

the Secretary may establish, as a branch of the Library, a regional medical library to serve the needs of such area.

"(e) Section 2101 shall be applicable to the acceptance and administration of gifts made for the benefit of the Library or for carrying out any of its functions, and the Board of Regents shall make recommendations to the Secretary relating to establishment within the Library of suitable memorials to the donors.

"(f) For purposes of this part the terms 'medicine' and 'medical', except when used in section 469, include preventive and therapeutic medicine, dentistry, pharmacy, hospitalization, nursing, public health, and the fundamental sciences related thereto, and other related fields of study, research, or activity.

"BOARD OF REGENTS

"SEC. 469. (a)(1) The Board of Regents of the National Library of Medicine consists of the Surgeons General of the Public Health Service, the Army, the Navy, and the Air Force, the Chief Medical Director of the Veterans' Administration, the Assistant Director for Biological, Behavioral, and Social Sciences of the National Science Foundation, and the Librarian of Congress, all of whom shall be ex officio members, and ten members appointed by the Secretary. The ten appointed members shall be selected from among leaders in the various fields of the fundamental sciences, medicine, dentistry, public health, hospital administration, pharmacology, health communications technology, or scientific or medical library work, or in public affairs. At least six of the appointed members shall be selected from among leaders in the fields of medical, dental, or public health research or education.

"(2) The Board shall annually elect one of the appointed members to serve as Chairman until the next election. The Secretary shall designate a member of the Library staff to act as executive secretary of the Board.

"(b) The Board shall advise, consult with, and make recommendations to the Secretary on matters of policy in regard to the Library, including such matters as the acquisition of materials for the Library, the scope, content, and organization of the Library's services, and the rules under which its materials, publications, facilities, and services shall be made available to various kinds of users. The Secretary shall include in the annual report of the Secretary to the Congress a statement covering the recommendations made by the Board and the disposition thereof. The Secretary may use the services of any member of the Board in connection with

matters related to the work of the Library, for such periods, in addition to conference periods, as the Secretary may determine.

"(c) Each appointed member of the Board shall hold office for a term of four years, except that any member appointed to fill a vacancy occurring prior to the expiration of the term for which the predecessor of such member was appointed shall be appointed for the remainder of such term. None of the appointed members shall be eligible for reappointment within one year after the end of the preceding term of such member.

"LIBRARY FACILITIES

"SEC. 470. There are authorized to be appropriated amounts sufficient for the erection and equipment of suitable and adequate buildings and facilities for use of the Library. The Administrator of General Services may acquire, by purchase, condemnation, donation, or otherwise, a suitable site or sites, selected by the Secretary in accordance with the direction of the Board, for such buildings and facilities and to erect thereon, furnish, and equip such buildings and facilities. The amounts authorized to be appropriated by this section include the cost of preparation of drawings and specifications, supervision of construction, and other administrative expenses incident to the work. The Administrator of General Services shall prepare the plans and specifications, make all necessary contracts, and supervise construction.

"Subpart 2—Financial Assistance

"AUTHORIZATION OF APPROPRIATIONS

"SEC. 472. For the purpose of grants and contracts under sections 475, 476, 477, 478, and 479, there are authorized to be appropriated $12,000,000 for fiscal year 1986, $13,000,000 for fiscal year 1987, and $14,000,000 for fiscal year 1988. Funds appropriated under this section shall remain available for such purposes until the end of the fiscal year immediately following the fiscal year for which they were appropriated.

"DEFINITIONS

"SEC. 473. As used in this subpart—

"(1) the term 'medical library' means a library related to the sciences related to health; and

"(2) the term 'sciences related to health' includes medicine, osteopathy, dentistry, and public health, and fundamental and applied sciences when related thereto.

"NATIONAL MEDICAL LIBRARIES ASSISTANCE ADVISORY BOARD

"SEC. 474. (a) The Board of Regents of the National Library of Medicine shall also serve as the National Medical Libraries Assistance Advisory Board (hereafter in this subpart referred to as the 'Board').

"(b) The Board shall advise and assist the Secretary in the preparation of general regulations and with respect to policy matters arising in the administration of this subpart.

"(c) The Secretary may use the services of any member of the Board, in connection with matters related to the administration of this part for such periods, in addition to conference periods, as the Secretary may determine.

"(d) Appointed members of the Board who are not otherwise in the employ of the United States, while attending conferences of the Board or otherwise serving at the request of the Secretary in connection with the administration of this subpart, shall be entitled to receive compensation, per diem in lieu of subsistence, and travel expenses in the same manner and under the same conditions as that prescribed under section 208(c) when attending conferences, traveling, or serving at the request of the Secretary in connection with the Board's function under this section.

"GRANTS FOR TRAINING IN MEDICAL LIBRARY SCIENCES

"SEC. 475. The Secretary shall make grants—

"(1) to individuals to enable them to accept traineeships and fellowships leading to postbaccalaureate academic degrees in the field of medical library science, in related fields pertaining to sciences related to health, or in the field of the communication of information;

"(2) to individuals who are librarians or specialists in information on sciences relating to health, to enable them to undergo intensive training or retraining so as to attain greater competence in their occupations (including competence in the fields of automatic data processing and retrieval);

"(3) to assist appropriate public and private nonprofit institutions in developing, expanding, and improving training programs in library science and the field of communications of information pertaining to sciences relating to health; and

"(4) to assist in the establishment of internship programs in established medical libraries meeting standards which the Secretary shall prescribe.

"ASSISTANCE FOR SPECIAL SCIENTIFIC PROJECTS, AND FOR RESEARCH AND DEVELOPMENT IN MEDICAL LIBRARY SCIENCE AND RELATED FIELDS

"SEC. 476. (a) The Secretary shall make grants to physicians and other practitioners in the sciences related to health, to scientists, and to public or nonprofit private institutions on behalf of such physicians, other practitioners, and scientists for the compilation of existing, or the writing of original, contributions relating to scientific, social, or cultural advancements in sciences related to health. In making such grants, the Secretary shall make appropriate arrangements under which the facilities of the Library and the facilities of libraries of public and private nonprofit institutions of higher learning may be made available in connection with the projects for which such grants are made.

"(b) The Secretary shall make grants to appropriate public or private nonprofit institutions and enter into contracts with appropriate persons, for purposes of carrying out projects of research, investigations, and demonstrations in the field of medical library science and related activities and for the development of new techniques, systems, and equipment, for processing, storing, retrieving,

and distributing information pertaining to sciences related to health.

"GRANTS FOR ESTABLISHING, EXPANDING, AND IMPROVING THE BASIC RESOURCES OF MEDICAL LIBRARIES AND RELATED INSTRUMENTALITIES

"SEC. 477. (a) The Secretary shall make grants of money, materials, or both, to public or private nonprofit medical libraries and related scientific communication instrumentalities for the purpose of establishing, expanding, and improving their basic medical library or related resources. A grant under this subsection may be used for—

"(1) the acquisition of books, journals, photographs, motion picture and other films, and other similar materials;

"(2) cataloging, binding, and other services and procedures for processing library resource materials for use by those who are served by the library or related instrumentality;

"(3) the acquisition of duplication devices, facsimile equipment, film projectors, recording equipment, and other equipment to facilitate the use of the resources of the library or related instrumentality by those who are served by it; and

"(4) the introduction of new technologies in medical librarianship.

"(b)(1) The amount of any grant under this section to any medical library or related instrumentality shall be determined by the Secretary on the basis of the scope of library or related services provided by such library or instrumentality in relation to the population and purposes served by it. In making a determination of the scope of services served by any medical library or related instrumentality, the Secretary shall take into account—

"(A) the number of graduate and undergraduate students making use of the resources of such library or instrumentality;

"(B) the number of physicians and other practitioners in the sciences related to health utilizing the resources of such library or instrumentality;

"(C) the type of supportive staffs, if any, available to such library or instrumentality;

"(D) the type, size, and qualifications of the faculty of any school with which such library or instrumentality is affiliated;

"(E) the staff of any hospital or hospitals or of any clinic or clinics with which such library or instrumentality is affiliated; and

"(F) the geographic area served by such library or instrumentality and the availability within such area of medical library or related services provided by other libraries or related instrumentalities.

"(2) Grants to medical libraries or related instrumentalities under this section shall be in such amounts as the Secretary may by regulation prescribe with a view to assuring adequate continuing financial support for such libraries or instrumentalities from other sources during and after the period for which grants are provided.

"GRANTS AND CONTRACTS FOR ESTABLISHMENT OF REGIONAL MEDICAL LIBRARIES

"SEC. 478. (a) The Secretary, with the advice of the Board, shall make grants to and enter into contracts with existing public or private nonprofit medical libraries so as to enable each of them to serve as the regional medical library for the geographical area in which it is located.

"(b) The uses for which grants and contracts under this section may be employed include the—

"(1) acquisition of books, journals, and other similar materials;

"(2) cataloging, binding, and other procedures for processing library resource materials for use by those who are served by the library;

"(3) acquisition of duplicating devices and other equipment to facilitate the use of the resources of the library by those who are served by it;

"(4) acquisition of mechanisms and employment of personnel for the speedy transmission of materials from the regional library to local libraries in the geographic area served by the regional library; and

"(5) planning for services and activities under this section.

"(c)(1) Grants and contracts under this section shall only be made to or entered into with medical libraries which agree—

"(A) to modify and increase their library resources, and to supplement the resources of cooperating libraries in the region, so as to be able to provide adequate supportive services to all libraries in the region as well as to individual users of library services; and

"(B) to provide loan services to qualified users and make available photoduplicated or facsimile copies of biomedical materials which qualified requesters may retain.

"(2) The Secretary, in awarding grants and contracts under this section, shall give priority to medical libraries having the greatest potential of fulfilling the needs for regional medical libraries. In determining the priority to be assigned to any medical library, the Secretary shall consider—

"(A) the adequacy of the library (in terms of collections, personnel, equipment, and other facilities) as a basis for a regional medical library; and

"(B) the size and nature of the population to be served in the region in which the library is located.

"(d) Grants and contracts under this section for basic resource materials to a library may not exceed—

"(1) 50 percent of the library's annual operating expense (exclusive of Federal financial assistance under this part) for the preceding year; or

"(2) in case of the first year in which the library receives a grant under this section for basic resource materials, 50 percent of its average annual operating expenses over the past three years (or if it had been in operation for less than three years, its annual operating expenses determined by the Secretary in accordance with regulations).

"FINANCIAL SUPPORT OF BIOMEDICAL SCIENTIFIC PUBLICATIONS

"SEC. 479. (a) The Secretary, with the advice of the Board, shall make grants to, and enter into appropriate contracts with, public or private nonprofit institutions of higher education and individual scientists for the purpose of supporting biomedical scientific publications of a nonprofit nature and to procure the compilation, writing, editing, and publication of reviews, abstracts, indices, handbooks, bibliographies, and related matter pertaining to scientific works and scientific developments.

"(b) Grants under this section in support of any single periodical publication may not be made for more than three years, except in those cases in which the Secretary determines that further support is necessary to carry out the purposes of this section.

"GRANT PAYMENTS; RECORDS AND AUDIT

"SEC. 480. (a) Payments under grants made under sections 475, 476, 477, 478, and 479 may be made in advance or by way of reimbursement and in such installments as the Secretary shall prescribe by regulation after consultation with the Board.

"(b)(1) Each recipient of a grant under this subpart shall keep such records as the Secretary shall prescribe, including records which fully disclose the amount and disposition by such recipient of the proceeds of such grant, the total cost of the project or undertaking in connection with which such grant is given or used, and the amount of that portion of the cost of the project or undertaking supplied by other sources, and such other records as will facilitate an effective audit.

"(2) The Secretary and the Comptroller General of the United States, or any of their duly authorized representatives, shall have access for the purpose of audit and examination to any books, documents, papers, and records of such recipients that are pertinent to any grant received under this subpart.

"PART E—OTHER AGENCIES OF NIH

"DIVISION OF RESEARCH RESOURCES

"SEC. 482. The general purpose of the Division of Research Resources is to strengthen and enhance the research environments of entities engaged in health-related research by developing and supporting essential research resources.

"JOHN E. FOGARTY INTERNATIONAL CENTER FOR ADVANCED STUDY IN THE HEALTH SCIENCES

"SEC. 483. The general purpose of the John E. Fogarty International Center for Advanced Study in the Health Sciences is to—

"(1) facilitate the assembly of scientists and others in the biomedical, behavioral, and related fields for discussion, study, and research relating to the development of health science internationally;

"(2) provide research programs, conferences, and seminars to further international cooperation and collaboration in the life sciences;

"(3) provide postdoctorate fellowships for research training in the United States and abroad and promote exchanges of senior scientists between the United States and other countries;

"(4) coordinate the activities of the National Institutes of Health concerned with the health sciences internationally; and

"(5) receive foreign visitors to the National Institutes of Health.

"PART F—AWARDS AND TRAINING

"NATIONAL RESEARCH SERVICE AWARDS

"SEC. 485. (a)(1) The Secretary shall—

"(A) provide National Research Service Awards for—

"(i) biomedical and behavioral research at the National Institutes of Health and the Alcohol, Drug Abuse, and Mental Health Administration in matters relating to the cause, diagnosis, prevention, and treatment of the diseases or other health problems to which the activities of the National Institutes of Health and Administration are directed;

"(ii) training at the National Institutes of Health and at the Administration of individuals to undertake such research;

"(iii) biomedical and behavioral research and health services research (including research in primary medical care) at public and nonprofit private entities; and

"(iv) pre-doctoral and post-doctoral training at public and private institutions of individuals to undertake biomedical and behavioral research; and

"(B) make grants to public and nonprofit private institutions to enable such institutions to make National Research Service Awards for research (and training to undertake biomedical and behavioral research) in the matters described in subparagraph (A)(i) to individuals selected by such institutions.

A reference in this subsection to the National Institutes of Health or the Alcohol, Drug Abuse, and Mental Health Administration shall be considered to include the institutes, agencies, divisions, and bureaus included in the National Institutes of Health or under the Administration, as the case may be.

"(2) National Research Service Awards may not be used to support residency training of physicians and other health professionals.

"(3) In awarding National Research Service Awards under this section, the Secretary shall take account of the Nation's overall need for biomedical research personnel by giving special consideration to physicians who agree to undertake a minimum of two years of biomedical research.

"(b)(1) No National Research Service Award may be made by the Secretary to any individual unless—

"(A) the individual has submitted to the Secretary an application therefor and the Secretary has approved the application;

"(B) the individual provides, in such form and manner as the Secretary shall by regulation prescribe, assurances satisfactory to the Secretary that the individual will meet the service requirement of subsection (c); and

"(C) in the case of a National Research Service Award for a purpose described in subsection (a)(1)(A)(iii), the individual has been sponsored (in such manner as the Secretary may by regulation require) by the institution at which the research or training under the award will be conducted.

An application for an award shall be in such form, submitted in such manner, and contain such information, as the Secretary may by regulation prescribe.

"(2) The making of grants under subsection (a)(1)(B) for National Research Service Awards shall be subject to review and approval by the appropriate advisory councils within the Department of Health and Human Services (A) whose activities relate to the research or training under the awards, or (B) for the entity at which such research or training will be conducted.

"(3) No grant may be made under subsection (a)(1)(B) unless an application therefor has been submitted to and approved by the Secretary. Such application shall be in such form, submitted in such manner, and contain such information, as the Secretary may by regulation prescribe. Subject to the provisions of this section (other than paragraph (1)), National Research Service Awards made under a grant under subsection (a)(1)(B) shall be made in accordance with such regulations as the Secretary shall prescribe.

"(4) The period of any National Research Service Award made to any individual under subsection (a) may not exceed—

"(A) five years in the aggregate for predoctoral training; and

"(B) three years in the aggregate for postdoctoral training;

unless the Secretary for good cause shown waives the application of such limit to such individual.

"(5) National Research Service Awards shall provide for such stipends, tuition, fees, and allowances (including travel and subsistence expenses and dependency allowances), adjusted periodically to reflect increases in the cost of living, for the recipients of the awards as the Secretary may deem necessary. A National Research Service Award made to an individual for research or research training at a non-Federal public or nonprofit private institution shall also provide for payments to be made to the institution for the cost of support services (including the cost of faculty salaries, supplies, equipment, general research support, and related items) provided such individual by such institution. The amount of any such payments to any institution shall be determined by the Secretary and shall bear a direct relationship to the reasonable costs of the institution for establishing and maintaining the quality of its biomedical and behavioral research and training programs.

"(c)(1) Each individual who is awarded a National Research Service Award (other than an individual who is a pre-baccalaureate student who is awarded a National Research Service Award for research training) shall, in accordance with paragraph (3), engage in health research or teaching or any combination thereof which is in accordance with the usual patterns of academic employment, for a period computed in accordance with paragraph (2).

"(2) For each month for which an individual receives a National Research Service Award which is made for a period in excess of twelve months, such individual shall engage in one month of health research or teaching or any combination thereof which is in accordance with the usual patterns of academic employment.

"(3) The requirement of paragraph (1) shall be complied with by any individual to whom it applies within such reasonable period of time, after the completion of such individual's award, as the Secretary shall by regulation prescribe. The Secretary shall by regulation prescribe the type of research and teaching in which an individual may engage to comply with such requirement and such other requirements respecting research and teaching as the Secretary considers appropriate.

"(4)(A) If any individual to whom the requirement of paragraph (1) is applicable fails, within the period prescribed by paragraph (3), to comply with such requirements, the United States shall be entitled to recover from such individual an amount determined in accordance with the formula—

$$A = \phi \frac{t-s}{t}$$

in which 'A' is the amount the United States is entitled to recover; 'ϕ' is the sum of the total amount paid under one or more National Research Service Awards to such individual; 't' is the total number of months in such individual's service obligation; and 's' is the number of months of such obligation served by such individual in accordance with paragraphs (1) and (2) of this subsection.

"(B) Any amount which the United States is entitled to recover under subparagraph (A) shall, within the three-year period beginning on the date the United States becomes entitled to recover such amount, be paid to the United States. Until any amount due the United States under subparagraph (A) on account of any National Research Service Award is paid, there shall accrue to the United States interest on such amount at a rate fixed by the Secretary of the Treasury after taking into consideration private consumer rates of interest prevailing on the date the United States becomes entitled to such amount.

"(5)(A) Any obligation of an individual under paragraph (1) shall be canceled upon the death of such individual.

"(B) The Secretary shall by regulation provide for the waiver or suspension of any such obligation applicable to any individual whenever compliance by such individual is impossible or would involve substantial hardship to such individual or would be against equity and good conscience.

"(d) There are authorized to be appropriated to make payments under National Research Service Awards and under grants for such awards $223,000,000 for fiscal year 1986, $235,000,000 for fiscal

year 1987, and $245,000,000 for fiscal year 1988. Of the amounts appropriated under this subsection—

"(1) not less than 15 percent shall be made available for payments under National Research Service Awards provided by the Secretary under subsection (a)(1)(A);

"(2) not less than 50 percent shall be made available for grants under subsection (a)(1)(B) for National Research Service Awards;

"(3) one-half of one percent shall be made available for payments under National Research Service Awards which (A) are made to individuals affiliated with entities which have received grants or contracts under section 780, 784, or 786, and (B) are for research in primary medical care; and one-half of one percent shall be made available for payments under National Research Service Awards made for health services research by the National Center for Health Services Research and Health Care Technology Assessment under section 304(a)(3); and

"(4) not more than 4 percent may be obligated for National Research Service Awards for periods of three months or less.

"VISITING SCIENTIST AWARDS

"SEC. 486. (a) The Secretary may make awards (hereafter in this section referred to as 'Visiting Scientist Awards') to outstanding scientists who agree to serve as visiting scientists at institutions of postsecondary education which have significant enrollments of disadvantaged students. Visiting Scientist Awards shall be made by the Secretary to enable the faculty and students of such institutions to draw upon the special talents of scientists from other institutions for the purpose of receiving guidance, advice, and instruction with regard to research, teaching, and curriculum development in the biomedical and behavioral sciences and such other aspects of these sciences as the Secretary shall deem appropriate.

"(b) The amount of each Visiting Scientist Award shall include such sum as shall be commensurate with the salary or remuneration which the individual receiving the award would have been entitled to receive from the institution with which the individual has, or had, a permanent or immediately prior affiliation. Eligibility for and terms of Visiting Scientist Awards shall be determined in accordance with regulations the Secretary shall prescribe.

"STUDIES RESPECTING BIOMEDICAL AND BEHAVIORAL RESEARCH PERSONNEL

"SEC. 487. (a) Within five years after the date of enactment of the Health Research Extension Act of 1985, and every five years thereafter, the Secretary shall, in accordance with subsection (b), arrange for the conduct of a study to—

"(1) establish (A) the Nation's overall need for biomedical and behavioral research personnel, (B) the subject areas in which such personnel are needed and the number of such personnel needed in each such area, and (C) the kinds and extent of training which should be provided such personnel;

"(2) assess (A) current training programs available for the training of biomedical and behavioral research personnel which are conducted under this Act, at or through national research institutes under the National Institutes of Health and institutes under the Alcohol, Drug Abuse, and Mental Health Administration, and (B) other current training programs available for the training of such personnel;

"(3) identify the kinds of research positions available to and held by individuals completing such programs;

"(4) determine, to the extent feasible, whether the programs referred to in clause (B) of paragraph (2) would be adequate to meet the needs established under paragraph (1) if the programs referred to in clause (A) of paragraph (2) were terminated; and

"(5) determine what modifications in the programs referred to in paragraph (2) are required to meet the needs established under paragraph (1).

"(b)(1) The Secretary shall request the National Academy of Sciences to conduct each study required by subsection (a) under an arrangement under which the actual expenses incurred by such Academy in conducting each such study will be paid by the Secretary. If the National Academy of Sciences is willing to do so, the Secretary shall enter into such an arrangement with such Academy for the conduct of each such study.

"(2) If the National Academy of Sciences is unwilling to conduct any such study under such an arrangement, then the Secretary shall enter into a similar arrangement with other appropriate nonprofit private groups or associations under which such groups or associations will conduct such study and prepare and submit the reports thereon as provided in subsection (c).

"(3) The National Academy of Sciences or other group or association conducting each study required by subsection (a) shall conduct each such study in consultation with the Director of NIH.

"(c) A report on the results of each study required under subsection (a) shall be submitted by the Secretary to the Committee on Energy and Commerce of the House of Representatives and the Committee on Labor and Human Resources of the Senate.

"PART G—GENERAL PROVISIONS

"INSTITUTIONAL REVIEW BOARDS; ETHICS GUIDANCE PROGRAM

"SEC. 489. (a) The Secretary shall by regulation require that each entity which applies for a grant, contract, or cooperative agreement under this Act for any project or program which involves the conduct of biomedical or behavioral research involving human subjects submit in or with its application for such grant, contract, or cooperative agreement assurances satisfactory to the Secretary that it has established (in accordance with regulations which the Secretary shall prescribe) a board (to be known as an 'Institutional Review Board') to review biomedical and behavioral research involving human subjects conducted at or supported by such entity in order to protect the rights of the human subjects of such research.

"(b)(1) The Secretary shall establish a program within the Department of Health and Human Services under which requests for

clarification and guidance with respect to ethical issues raised in connection with biomedical or behavioral research involving human subjects are responded to promptly and appropriately.

"(2) The Secretary shall establish a process for the prompt and appropriate response to information provided to the Director of NIH respecting incidences of violations of the rights of human subjects of research for which funds have been made available under this Act. The process shall include procedures for the receiving of reports of such information from recipients of funds under this Act and taking appropriate action with respect to such violations.

"PEER REVIEW REQUIREMENTS

"SEC. 490. (a)(1) The Secretary, acting through the Director of NIH, shall by regulation require appropriate technical and scientific peer review of—

"(A) grants and cooperative agreements under this Act for biomedical and behavioral research; and

"(B) biomedical and behavioral research and development contracts to be administered through the National Institutes of Health.

"(2) Regulations promulgated under paragraph (1) shall require that the review of grants, contracts, and cooperative agreements required by the regulations be conducted—

"(A) in a manner consistent with the system for scientific peer review applicable on the date of the effective date of the Health Research Extension Act of 1985 to grants under this Act for biomedical and behavioral research;

"(B) to the extent practical, by peer review groups performing such review on or before such date; and

"(C) in accordance with section 405(c)(3).

"(b) The Director of NIH shall establish procedures for periodic, technical, and scientific peer review of research at the National Institutes of Health. Such procedures shall require that—

"(1) the reviewing entity be provided a written description of the research to be reviewed; and

"(2) the reviewing entity provide the advisory council of the national research institute involved with such description and the results of the review by the entity.

"PROTECTION AGAINST SCIENTIFIC FRAUD

"SEC. 491. (a) The Secretary shall by regulation require that each entity which applies for a grant, contract, or cooperative agreement under this Act for any project or program which involves the conduct of biomedical or behavioral research submit in or with its application for such grant, contract, or cooperative agreement assurances satisfactory to the Secretary that such entity—

"(1) has established (in accordance with regulations which the Secretary shall prescribe) an administrative process to review reports of scientific fraud in connection with biomedical and behavioral research conducted at or sponsored by such entity; and

"(2) will report to the Secretary any investigation of alleged scientific fraud which appears substantial.

"(b) The Director of NIH shall establish a process for the prompt and appropriate response to information provided the Director of NIH respecting scientific fraud in connection with projects for which funds have been made available under this Act. The process shall include procedures for the receiving of reports of such information from recipients of funds under this Act and taking appropriate action with respect to such fraud.

"RESEARCH ON PUBLIC HEALTH EMERGENCIES

"SEC. 492. (a) If the Secretary determines, after consultation with the Director of NIH, the Commissioner of the Food and Drug Administration, or the Director of the Centers for Disease Control, that a disease or disorder constitutes a public health emergency, the Secretary, acting through the Director of NIH—

"(1) shall expedite the review by advisory councils under section 406 and the peer review required by regulations under section 490 of grants for research on such disease or disorder or proposals for contracts for such research;

"(2) shall exercise the authority in section 3709 of the Revised Statutes (41 U.S.C. 5) respecting public exigencies to waive the advertising requirements of such section in the case of proposals for contracts for such research;

"(3) may provide administrative supplemental increases in existing grants and contracts to support new research relevant to such disease or disorder; and

"(4) shall disseminate, to health professionals and the public, information on the cause, prevention, and treatment of such disease or disorder that has been developed in research assisted under this section.

The amount of an increase in a grant or contract provided under paragraph (3) may not exceed one-half the original amount of the grant or contract.

"(b) Not later than 90 days after the end of a fiscal year, the Secretary shall report to the Committee on Energy and Commerce of the House of Representatives and the Committee on Labor and Human Resources of the Senate on actions taken under subsection (a) in such fiscal year.

"ANIMALS IN RESEARCH

"SEC. 493. (a) The Secretary, acting through the Director of NIH, shall establish guidelines for the following:

"(1) The proper care of animals to be used in biomedical and behavioral research.

"(2) The proper treatment of animals while being used in such research. Guidelines under this paragraph shall specify—

"(A) the appropriate use of tranquilizers, analgesics, anesthetics, paralytics, and euthanasia for animals in such research; and

"(B) appropriate pre-surgical and post-surgical veterinary medical and nursing care for animals in such research.

Such guidelines shall not be construed to prescribe methods of research.

"(3) The organization and operation of animal care committees in accordance with subsection (b).

"(b)(1) Guidelines of the Secretary under subsection (a)(3) shall require animal care committees at each entity which conducts biomedical and behavioral research with funds provided under this Act (including the National Institutes of Health and the national research institutes) to assure compliance with the guidelines established under subsection (a).

"(2) Each animal care committee shall be appointed by the chief executive officer of the entity for which the committee is established, shall be composed of not fewer than three members, and shall include at least one individual who has no association with such entity and at least one doctor of veterinary medicine.

"(3) Each animal care committee of a research entity shall—

"(A) review the care and treatment of animals in all animal study areas and facilities of the research entity at least semiannually to evaluate compliance with applicable guidelines established under subsection (a) for appropriate animal care and treatment;

"(B) keep appropriate records of reviews conducted under subparagraph (A); and

"(C) for each review conducted under subparagraph (A), file with the Director of NIH at least annually (i) a certification that the review has been conducted, and (ii) reports of any violations of guidelines established under subsection (a) or assurances required under paragraph (1) which were observed in such review and which have continued after notice by the committee to the research entity involved of the violations.

Reports filed under subparagraph (C) shall include any minority views filed by members of the committee.

"(c) The Director of NIH shall require each applicant for a grant, contract, or cooperative agreement involving research on animals which is administered by the National Institutes of Health or any national research institute to include in any application or contract proposal submitted after the expiration of the twelve-month period beginning on the effective date of this section—

"(1) assurances satisfactory to the Director of NIH that—

"(A) the applicant meets the requirements of the guidelines established under paragraphs (1) and (2) of subsection (a) and has an animal care committee which meets the requirements of subsection (b); and

"(B) scientists, animal technicians, and other personnel involved with animal care, treatment, and use by the applicant have available to them instruction or training in the humane practice of animal maintenance and experimentation, and the concept, availability, and use of research or testing methods that limit the use of animals or limit animal distress; and

"(2) a statement of the reasons for the use of animals in the research to be conducted with funds provided under such grant or contract.

Notwithstanding subsection (a)(2) of section 553 of title 5, United States Code, regulations under this subsection shall be promulgated

in accordance with the notice and comment requirements of such section.

"(d) If the Director of NIH determines that—

"(1) the conditions of animal care, treatment, or use in an entity which is receiving a grant, contract, or cooperative agreement involving research on animals under this title do not meet applicable guidelines established under subsection (a);

"(2) the entity has been notified by the Director of NIH of such determination and has been given a reasonable opportunity to take corrective action; and

"(3) no action has been taken by the entity to correct such conditions;

the Director of NIH shall suspend or revoke such grant or contract under such conditions as the Director determines appropriate.

"(e) No guideline or regulation promulgated under subsection (a) or (c) may require a research entity to publicly disclose trade secrets or commercial or financial information which is privileged or confidential.

"USE OF APPROPRIATIONS UNDER THIS TITLE

"SEC. 494. Appropriations to carry out the purposes of this title shall be available for the acquisition of land or the erection of buildings only if so specified. Such appropriations, unless otherwise expressly provided, may be expended in the District of Columbia for—

"(1) personal services;

"(2) stenographic recording and translating services;

"(3) travel expenses (including the expenses of attendance at meetings when specifically authorized by the Secretary);

"(4) rental;

"(5) supplies and equipment;

"(6) purchase and exchange of medical books, books of reference, directories, periodicals, newspapers, and press clippings;

"(7) purchase, operation, and maintenance of passenger motor vehicles;

"(8) printing and binding (in addition to that otherwise provided by law); and

"(9) all other necessary expenses in carrying out this title.

Such appropriations may be expended by contract if deemed necessary, without regard to section 3709 of the Revised Statutes (41 U.S.C. 5).

"GIFTS

"SEC. 495. The Secretary may, in accordance with section 2101, accept conditional gifts for the National Institutes of Health or a national research institute or for the acquisition of grounds or for the erection, equipment, or maintenance of facilities for the National Institutes of Health or a national research institute. Donations equal to or in excess of $50,000 for the National Institutes of Health or a national research institute for carrying out the purposes of this title may be acknowledged by the establishment within the National Institutes of Health or national research institute of suitable memorials to the donors.

"FETAL RESEARCH

"SEC. 496. (a) The Secretary may not conduct or support any research or experimentation, in the United States or in any other country, on a nonviable living human fetus ex utero or a living human fetus ex utero for whom viability has not been ascertained unless the research or experimentation—

"(1) may enhance the well-being or meet the health needs of the fetus or enhance the probability of its survival to viability; or

"(2) will pose no added risk of suffering, injury, or death to the fetus and the purpose of the research or experimentation is the development of important biomedical knowledge which cannot be obtained by other means.

"(b) In administering the regulations for the protection of human research subjects which—

"(1) apply to research conducted or supported by the Secretary;

"(2) involve living human fetuses in utero; and

"(3) are published in section 46.208 of part 46 of title 45 of the Code of Federal Regulations;

or any successor to such regulations, the Secretary shall require that the risk standard (published in section 46.102(g) of such part 46 or any successor to such regulations) be the same for fetuses which are intended to be aborted and fetuses which are intended to be carried to term.

"(c)(1) The Biomedical Ethics Advisory Committee appointed under section 381 shall conduct a study of the nature, advisability, and biomedical and ethical implications of exercising any waiver of the risk standard published in section 46.102(g) of such part 46 (or any successor to such regulations). The Committee shall complete the study and report its findings to the Biomedical Ethics Board established under section 381 not later than the expiration of thirty months after the effective date of this section. The report shall include the recommendations, if any, of the Committee on the advisability of the authority for such a waiver and the circumstances under which such a waiver might be granted. The Biomedical Ethics Board shall transmit the report to the Secretary, the Committee on Energy and Commerce of the House of Representatives, and the Committee on Labor and Human Resources of the Senate.

"(2) During the thirty-six-month period beginning on the effective date of this section, the Secretary may not grant (under section 46.211 of part 45 of title 46 of the Code of Federal Regulations or any successor to such section) a modification or waiver for fetal research.

"(3) Effective October 31, 1988, paragraph (2) is repealed.

"CONSTRUCTION OF TITLE

"SEC. 497. This title shall not be construed as limiting (1) the functions or authority of the Secretary under section 301 or of any officer or agency of the United States, relating to the study, prevention, diagnosis, and treatment of any disease for which a separate national research institute is established under this title, or (2) the expenditure of any funds therefor.".

CONFORMING AMENDMENTS

SEC. 3. (a)(1) The National Advisory Health Council established under section 217 is terminated.

(2) Section 217(a) is amended—

(A) in the first sentence—

(i) by striking out "National Advisory Health Council, the National Advisory Mental Health Council, the National Advisory Council on Alcohol Abuse and Alcoholism, and the National Advisory Dental Research Council" and inserting in lieu thereof "National Advisory Mental Health Council and the National Advisory Council on Alcohol Abuse and Alcoholism"; and

(ii) by striking out "by the Surgeon General with the approval of the Secretary of Health, Education, and Welfare" and inserting in lieu thereof "by the Secretary";

(B) in the second sentence—

(i) by striking out "in the case of the National Advisory Health Council, are skilled in the sciences related to health; and"

(ii) by striking out "the National Advisory Mental Health Council, the National Advisory Council on Alcohol Abuse and Alcoholism, the National Advisory Heart Council, and the National Advisory Dental Research Council" and inserting in lieu thereof "the National Advisory Mental Health Council and the National Advisory Council on Alcohol Abuse and Alcoholism"; and

(iii) by striking out ", alcohol abuse and alcoholism, and dental diseases and conditions" and inserting in lieu thereof "and alcohol abuse and alcoholism"; and

(C) by striking out the third sentence.

(3) Subsection (b) of section 217 is repealed and subsections (c) through (e) and subsection (g) are redesignated as subsections (b) through (e), respectively.

(4) Section 222(c) is amended to read as follows:

"(c) Upon appointment of any such council or committee, the Secretary may delegate to such council or committee such advisory functions relating to grants-in-aid for research or training projects or programs, in the areas or fields with which such council or committee is concerned, as the Secretary determines to be appropriate.".

(5) Section 301(a) is amended—

(A) in paragraph (3), by striking out "as are recommended" through "for such fiscal year" and inserting in lieu thereof "as are recommended by the advisory council to the entity of the Department supporting such projects or, in the case of mental health projects, by the National Advisory Mental Health Council; and make, upon recommendation of the advisory council to the entity of the department involved or the National Advisory Mental Health Council, grants-in-aid to public or nonprofit universities, hospitals, laboratories, and other institutions for the general support of their research"; and

(B) in paragraph (8), by striking out "recommendations of the National Advisory Health Council" through "as he deems"

and inserting in lieu thereof "recommendations of the advisory councils to the entities of the department involved or, with respect to mental health, the National Advisory Mental Health Council, such additional means as the Secretary considers".

(6) Section 1122(a) is amended by striking out "under section 441".

(b) Parts I and J of title III are repealed.

(c) Section 8(w) of the Orphan Drug Act is repealed.

(d) Section 506 is amended by adding at the end thereof the following new subsection:

"(e)(1) If the direct cost of a grant or contract (described in subsection (a)) to be made does not exceed $50,000, the Secretary may make such grant or cooperative agreement only if such grant or cooperative agreement is recommended after peer review required by regulations under subsections (a) and (b).

"(2) If the direct cost of a grant or contract (described in subsection (a)) to be made equals or exceeds $50,000, the Secretary may make such grant or cooperative agreement only if such grant or cooperative agreement is recommended after peer review required by regulations under subsections (a) and (b), and is recommended by the National Advisory Mental Health Council, the National Advisory Council on Alcohol Abuse and Alcoholism, or the National Advisory Council on Drug Abuse, as is appropriate.".

PLAN FOR RESEARCH INVOLVING ANIMALS

SEC. 4. (a) The Director of the National Institutes of Health shall establish a plan for—

(1) research to be conducted by or through the National Institutes of Health and the national research institutes into methods of biomedical research and experimentation—

(A) which do not require the use of animals;

(B) which reduce the number of animals used in such research; or

(C) which produce less pain and distress in such animals than methods currently in use;

(2) establishing the validity and reliability of the methods described in subparagraph (A);

(3) the development of such methods which have been found to be valid and reliable; and

(4) the training of scientists in the use of such methods.

The plan required by this paragraph shall be prepared not later than October 1, 1986.

(b) The Director of the National Institutes of Health shall take such actions as may be appropriate to convey to scientists and others involved with research or experimentation involving animals information respecting the methods found to be valid and reliable under subsection (a)(2).

(c) The Director of the National Institutes of Health shall establish within the National Institutes of Health an Interagency Coordinating Committee to assist the Director of the National Institutes of Health in the development of the plan required by subsection (a). The Director of each national research institute shall serve on the Committee.

RESEARCH ON LUPUS ERYTHEMATOSUS

SEC. 5. (a) The Secretary shall establish a Lupus Erythematosus Coordinating Committee to plan, develop, coordinate, and implement comprehensive Federal initiatives in research on Lupus Erythematosus.

(b)(1) The Committee shall be composed of—

(A) the Director of the National Institute of Neurological and Communicative Disorders and Stroke (or the designee of such Director);

(B) the Director of the National Institute of Allergy and Infectious Diseases (or the designee of such Director);

(C) the Director of the National Institute of Arthritis and Musculoskeletal and Skin Diseases (or the designee of such Director);

(D) the Director of the National Institute of General Medical Sciences (or the designee of such Director);

(E) the Director of the National Heart, Lung, and Blood Institute (or the designee of such Director);

(F) the Director of the National Institute of Diabetes and Digestive and Kidney Diseases (or the designee of such Director); and

(G) the Director of the Centers for Disease Control (or the designee of such Director).

(2) The Committee shall meet at least four times a year. The Secretary shall designate as chairman of the Committee the Director of the National Institute of Arthritis and Musculoskeletal and Skin Diseases.

(c) The Committee shall prepare a report for Congress on its activities. The report shall include a description of research projects on Lupus Erythematosus conducted or supported by Federal agencies in the fiscal year for which the report is made, the nature and purpose of each such project, the amounts expended for each such project, and an identification of the entity which conducted the research under each such project. Such report shall be submitted not later than 18 months after the date of the effective date of this Act. The Committee shall terminate one month after the report is submitted.

NATIONAL RESEARCH SERVICE AWARD STUDY

SEC. 6. (a) The Secretary of Health and Human Services shall conduct a study of—

(1) the effect of the service obligation requirement of section 485(c) of the Public Health Service Act on the number and quality of individuals who apply for National Research Service Awards;

(2) the effect of section 485(c)(4) of such Act on the number of persons who engage in health research or training as a career;

(3) the number of persons who receive National Research Service Awards and who engage in health research or training as a career; and

(4) the effectiveness of the grant authority under section 485(a)(1)(B) of such Act in encouraging individuals to engage in health research and training as a career.

(b) The Secretary shall complete the study required by subsection (a) within one year after the effective date of this Act and shall report the results of the study to the Committee on Energy and Commerce of the House of Representatives and the Committee on Labor and Human Resources of the Senate.

INTERAGENCY COMMITTEE ON SPINAL CORD INJURY

SEC. 7. (a) Within 90 days after the effective date of this Act, the Secretary of Health and Human Services shall establish in the National Institute of Neurological and Communicative Diseases and Stroke an Interagency Committee on Spinal Cord Injury (hereafter in this section referred to as the "Interagency Committee"). The Interagency Committee shall plan, develop, coordinate, and implement comprehensive Federal initiatives in research on spinal cord injury and regeneration.

(b)(1) The Interagency Committee shall consist of representatives from—

(A) the National Institute on Neurological and Communicative Disorders and Stroke;

(B) the Department of Defense;

(C) the Department of Education;

(D) the Veterans' Administration;

(E) the Office of Science and Technology Policy; and

(F) the National Science Foundation;

designated by the heads of such entities.

(2) The Interagency Committee shall meet at least four times. The Secretary of Health and Human Services shall select the Chairman of the Interagency Committee from the members of the Interagency Committee.

(c) Within the 18 months after the effective date of this Act, the Interagency Committee shall prepare and transmit to the Congress a report concerning its activities under this section. The report shall include a description of research projects on spinal cord injury and regeneration conducted or supported by Federal agencies during such 18-month period, the nature and purpose of each such project, the amounts expended for each such project, and an identification of the entity which conducted the research under each such project.

(d) The Interagency Committee shall terminate 90 days after the date on which the Interagency Committee transmits the report required by subsection (c) to the Congress.

STUDY OF PERSONNEL FOR HEALTH NEEDS OF THE ELDERLY

SEC. 8. (a) The Secretary shall conduct a study on the adequacy and availability of personnel to meet the current and projected health needs (including needs for home and community-based care) of elderly Americans through the year 2020.

(b) The Secretary shall report the results of the study to the Committee on Energy and Commerce of the House of Representatives and the Committee on Labor and Human Resources of the Senate by March 1, 1986. The report on the study shall contain recommendations on—

(1) the number of primary care physicians, dentists, and other health personnel needed to provide adequate care for the elderly;

(2) the training needs of physicians and dentists (including specialists) and other health personnel to provide care responsive to the particular needs of the elderly;

(3) necessary changes in medicare and other third party reimbursement programs necessary to support training of primary care and other physicians to meet the needs of the elderly; and

(4) necessary program changes in third party reimbursement programs (including changes in medicare programs) to support training of other health personnel in the care of the elderly.

INTERAGENCY COMMITTEE ON LEARNING DISABILITIES

SEC. 9. (a) Not later than 90 days after the effective date of this Act, the Director of the National Institutes of Health shall establish an Interagency Committee on Learning Disabilities to review and assess Federal research priorities, activities, and findings regarding learning disabilities (including central nervous system dysfunction in children).

(b) The Committee shall be composed of such representatives as the Director may designate, but shall include representatives from the National Institute of Neurological and Communicative Disorders and Stroke, the National Institute of Child Health and Human Development, the National Institute of Allergy and Infectious Diseases, the National Eye Institute, the National Institute of Environmental Health Sciences, the Division of Research Resources of the National Institutes of Health, and the National Institute of Mental Health.

(c) Not later than 18 months after the effective date of this Act, the Committee shall report to the Congress on its activities under subsection (a) and shall include in the report—

(1) the number of persons affected by learning disabilities and the demographic data which describes such persons;

(2) a description of the current research findings on the cause, diagnosis, treatment, and prevention of learning disabilities; and

(3) recommendations for legislation and administrative actions—

(A) to increase the effectiveness of research on learning disabilities and to improve the dissemination of the findings of such research; and

(B) respecting specific priorities for research in the cause, diagnosis, treatment, and prevention of learning disabilities.

(d) The Committee shall terminate 90 days after the date of the submission of the report under subsection (c).

REVIEW OF DISEASE RESEARCH PROGRAMS OF THE NATIONAL INSTITUTE OF DIABETES AND DIGESTIVE AND KIDNEY DISEASES

SEC. 10. The Secretary of Health and Human Services shall conduct an administrative review of the disease research programs of

the National Institute of Diabetes and Digestive and Kidney Diseases to determine if any of such programs could be more effectively and efficiently managed by other national research institutes. The Secretary shall complete such review within the one-year period beginning on the effective date of this Act.

BIOMEDICAL ETHICS

SEC. 11. Title III (as amended by section 3(b)) is amended by adding at the end the following:

"Part I—Biomedical Ethics

"SEC. 381. (a) There is established in the legislative branch of the Government the Biomedical Ethics Board (hereinafter referred to as the 'Board').

"(b)(1) The Board shall consist of twelve members as follows:

"(A) Six Members of the Senate appointed as follows: Three members appointed by the Majority Leader of the Senate from the majority party and three members appointed by the Minority Leader from the minority party.

"(B) Six Members of the House of Representatives appointed by the Speaker of the House of Representatives, three from the majority party and three from the minority party.

"(2) The term of office of a member of the Board shall expire when the member leaves the office of Senator or Representative, as the case may be, or upon the expiration of eight years after the date of the member's appointment to the Board, whichever occurs first.

"(3) Vacancies in the membership of the Board shall not affect the power of the remaining members to execute the functions of the Board and shall be filled in the same manner as in the case of the original appointment.

"(4) The Board shall select a chairman and a vice chairman from among its members at the beginning of each Congress. The vice chairman shall act as chairman in the absence of the chairman or in the event of the incapacity of the chairman. The chairmanship and vice chairmanship shall alternate between the Senate and the House of Representatives with each Congress. The chairman during each even-numbered Congress shall be selected by the Members of the House of Representatives on the Board from among their number. The vice chairman during each Congress shall be chosen in the same manner from that House of Congress other than the House of Congress of which the chairman is a Member.

"(5) The Board shall meet once every three months unless such meeting is dispensed with by the chairman, and may meet at any time upon the request of four or more members of the Board or upon the call of the chairman.

"(c)(1) The Board shall study and report to the Congress on a continuing basis on the ethical issues arising from the delivery of health care and biomedical and behavioral research, including the protection of human subjects of such research and developments in genetic engineering (including activities in recombinant DNA technology) which have implications for human genetic engineering.

"(2)(A) Except as provided in subparagraph (B), an annual report shall be transmitted to the Congress identifying the issues which were the subject of the study conducted under paragraph (1) and identifying areas, programs, and practices of medicine and biomedical and behavioral research which have significant ethical implications and which would be appropriate subjects for study.

"(B) A report on research and developments in genetic engineering (including activities in recombinant DNA technology) which have implications for human genetic engineering shall be transmitted to the Congress not later than eighteen months after the appointment of the Committee under subsection (d).

"(d)(1) To conduct the studies and make the reports required by subsection (c), the Board shall appoint a Biomedical Ethics Advisory Committee (hereinafter referred to as the 'Committee'). The Committee shall consist of fourteen members as follows:

"(A) Four of the members shall be appointed by the Board from individuals who are distinguished in biomedical or behavioral research.

"(B) Three of the members shall be appointed by the Board from individuals who are distinguished in the practice of medicine or otherwise distinguished in the provision of health care.

"(C) Five of the members shall be appointed by the Board from individuals who are distinguished in one or more of the fields of ethics, theology, law, the natural sciences (other than the biomedical or behavioral sciences), the social sciences, the humanities, health administration, government, and public affairs.

"(D) Two of the members shall be appointed by the Board from individuals who are representatives of citizens with an interest in biomedical ethics but who possess no specific expertise.

"(2)(A) The Committee, by majority vote, shall elect from its members a chairman and a vice chairman and appoint an executive director who shall serve for such time and under such conditions as the Committee may prescribe. In the absence of the chairman, or in the event of the incapacity of the chairman, the vice chairman shall act as chairman.

"(B) The term of office of each member of the Committee shall be four years, except that any such member appointed to fill a vacancy occurring prior to the expiration of the term for which such member's predecessor was appointed shall be appointed for the remainder of such term. Terms of the members shall be staggered so as to establish a rotating membership.

"(C) The members of the Committee shall receive no pay for their services as members of the Committee, but shall be allowed necessary travel expenses (or, in the alternative, mileage for use of privately owned vehicles and a per diem in lieu of subsistence at not to exceed the rate prescribed in sections 5702 and 5704 of title 5, United States Code) and other necessary expenses incurred by them in the performance of duties as a member of the Committee, without regard to the provisions of subchapter 1 of chapter 57 and section 5731 of title 5, United States Code, and regulations promulgated thereunder.

"(D) The executive director of the Committee, with the approval of the Committee, may employ such staff and consultants as necessary to prepare studies and reports for the Committee.

"(3)(A) The Committee may, for the purpose of carrying out its functions, hold such public hearings, sit and act at such times and places, and take such testimony, as the Committee considers appropriate.

"(B) Upon request of the Committee, the head of any Federal agency is authorized to detail, on a reimbursable basis, any of the personnel of such agency to the Committee to assist the Committee in carrying out its functions.

"(C) The Committee may secure directly from any department or agency of the United States information necessary to enable it to carry out its functions. Upon request of the chairman of the Committee, the head of such department or agency shall furnish such information to the Committee.

"(D) The Committee may accept, use, and dispose of gifts or donations or services or property.

"(E) The Committee may use the United States mails in the same manner and under the same conditions as other departments and agencies of the United States.

"(e) To enable the Board and the Committee to carry out their functions there are authorized to be appropriated $2,000,000 for fiscal year 1986, $2,500,000 for fiscal year 1987, and $3,000,000 for fiscal year 1988.".

EFFECTIVE DATE

SEC. 12. This Act and the amendments made by this Act shall take effect October 1, 1985.

VII. BUDGET ESTIMATE

U.S. CONGRESS,
CONGRESSIONAL BUDGET OFFICE,
Washington, DC, July 1, 1985.

Hon. ORRIN G. HATCH,
Chairman, Committee on Labor and Human Resources, U.S. Senate, Washington, DC.

DEAR MR. CHAIRMAN: The Congressional Budget Office has prepared the attached cost estimate for S. 1309, the Health Research Extension Act of 1985, as ordered reported by the Senate Committee on Labor and Human Resources on June 27, 1985.

If you wish further details on this estimate, we will be pleased to provide them.

With best wishes,
Sincerely,

RUDOLPH G. PENNER.

CONGRESSIONAL BUDGET OFFICE COST ESTIMATE

1. Bill number: S. 1309.
2. Bill title: Health Research Amendments of 1985.
3. Bill status: As ordered reported by the Senate Committee on Labor and Human Resources on June 27, 1985.

4. Bill purpose: To amend the Public Health Service Act to revise and extend the authorities under that Act relating to the National Institutes of Health (NIH) and National Research Institutes.

5. Estimated cost to the Federal Government:

[By fiscal year, in millions of dollars]

	1986	1987	1988	1989	1990
Authorization levels:					
National Cancer Institute	1,194	1,270.0	1,344	.....	.....
Control Programs	68	74.0	80	.....	.....
National Heart, Lung, and Blood Institute	809	871.0	927	.....	.....
Control Programs	82	90.0	98	.....	.....
Medical Library Science Financial Assistance	12	13.0	14	.....	.....
National Research Service Awards	223	235.0	245	.....	.....
Biomedical Ethics Board	2	2.5	3	.....	.....
National Institute of Arthritis and Musculoskeletal and Skin Diseases	3	3.0	3	3.0	3
Total authorization levels	2,393	2,558.5	2,714	3.0	3
Estimated outlays:					
National Cancer Institute	577	1,126.0	1,284	687	117
Control Programs	33	65.0	75	41	7
National Heart, Lung, and Blood Institute	323	750.0	878	551	96
Control Programs	33	77.0	91	58	10
Medical Library Science Financial Assistance	8	12.0	13	5	1
National Research Service Awards	12	186.0	234	230	41
Biomedical Ethics Board	2	2.5	3	.....	.....
National Institute of Arthritis and Musculoskeletal and Skin Diseases	3	3.0	3	3	3
Total estimated outlays	991	2,221.5	2,581	1,575	275

The costs of this bill fall within function 550.

Basis of estimate: All authorization levels are stated in the bill. CBO assumes that all stated authorized amounts are fully appropriated at the beginning of each fiscal year. Outlays are estimated using spendout rates computed by CBO on the basis of recent program data.

This bill would establish a new National Institute of Arthritis and Musculoskeletal and Skin Disease within NIH. Arthritis, musculoskeletal, and skin disease research currently takes place within the National Institute of Arthritis, Diabetes, and Digestive and Kidney Disease. According to Committee staff, the new institute would result from restructuring the current program. Committee staff has indicated that the Committee's intent is to redirect funds to the new institute that otherwise would have been appropriated to the current program for arthritis, musculoskeletal, and skin disease research. No additional appropriations are requested for research activities. While no specific authorization for administrative costs is stated in the bill, NIH has estimated that 36 new administrative positions would be required for the new institute at a cost of about $3 million in each fiscal year. Administrative costs could be higher or lower depending on the actual number of additional personnel hired.

With this bill, certain NIH activities (research centers, advisory boards, and demonstration projects) that previously had specific authorizations for appropriations would now invoke the authorization

given under the general powers and duties of the Public Heath Service.

6. Estimated cost to state and local governments: The budgets of state and local governments would not be affected directly by the enactment of this bill

7. Estimate comparison: CBO prepared an estimate on May 20, 1985 for H.R. 2409, the Health Research Extension Act of 1985, as ordered reported by the House Committee on Energy and Commerce. H.R. 2409 creates a new National Institute of Nursing that is not authorized in S. 1309. H.R. 2409 reauthorizes programs for one year while S. 1309 reauthorizes programs for three years. Authorization levels in the two bills differ.

8. Previous CBO estimate: None.

9. Estimate prepared by: Carmela Pena.

10. Estimate approved by: James L. Blum, Assistant Director for Budget Analysis.

VIII. Administration Views

The Secretary of Health and Human Services,
Washington, DC, July 8, 1985.

Hon. Orrin G. Hatch,
Chairman, Committee on Labor and Human Resources, U.S. Senate, Washington, DC.

Dear Mr. Chairman: This is in response to your request for a report on S. 1309, a bill "To amend the Public Health Service Act to revise and extend the authorities under that Act relating to the National Institutes of Health and National Research Institutes, and for other purposes."

In summary, we are opposed to enactment of S. 1309. We believe that the general authority of section 301 of the Public Health Service Act is preferable to the bill's approach of imposing numerous organizational restrictions and requirements on the management and operation of biomedical research.

While we recognize your efforts to reduce the negative impact on the National Institutes of Health (NIH) proposed by the companion House measure, we oppose the bill because it restricts NIH flexibility essential to the proper conduct of science.

All of the proposed organizational entities, structures, requirements, positions, and reports mandated by S. 1309 undermine NIH's scientific discretion and thus threaten the continued success of this nation's biomedical research efforts. We urge you to reduce the intrusivenes of S. 1309 on the ability of NIH to remain the crown jewel in our nation's biomedical research effort.

We are advised by the Office of Management and Budget that there is no objection to the presentation of this report and that enactment of S. 1309 would not be in accord with the program of the President.

Sincerely,

Margaret M. Heckler,
Secretary.

IX. Regulatory Impact Statement

The Committee has determined that there will be minimal increase in regulatory and paperwork burden imposed by this bill. The establishment of a new National Institute of Arthritis and Musculoskeletal and Skin Diseases will require some adminstrative changes. Provisions relating to the use of animals in research will entail the development of minimal additional regulations.

Other revisions of statutory authorities within the National Institutes of Health can be accomplished within present regulations.

X. Section-by-Section Analysis

S. 1309—Health Research Extension Act of 1985 as Reported by the Senate Committee on Labor and Human Resources

Section 1 of the bill cites the Act as the "Health Research Extension Act of 1985"; identifies all references in the bill as being made to provisions of the Public Health Service Act (PHSA), except as otherwise specifically provided; and sets forth the table of contents of the bill.

Section 2 of the bill is a complete revision of Title IV of the PHSA. It has seven parts, dealing with (A) NIH as a whole; (B) the research institutes generally; (C) each research institute specifically; (D) the National Library of Medicine; (E) other NIH agencies; (F) awards and training; and (G) general provisions.

The new Part A of Title IV (Sec. 401–403) outlines the organization of the National Institutes of Health as a agency of the Public Health Service and lists the research institutes and other entities that are agencies of NIH. It grants to the Secretary authority to estalish, reorganize, or abolish research institutes after appropriate notification to Congress. Section 402 establishes the position of the Director of NIH and outlines the responsibilites and functions of that office, including the requirement to assure that intramural research is subject to peer review. This section also establishes the position of the Associate Director of Prevention, who is responsible for promoting and coordinating the disease prevention research programs of the research institutes. Section 403 requires the Director to prepare a biennial report for submission to the President and to Congress.

The new Part B of Title IV (Sec. 405–408) sets forth general provisions respecting the research institutes. Section 405 provides for the appointment of the Directors of the various research institutes and outlines their responsibilities and functions, including the authority to make grants and cooperative agreements of less than $50,000 without referral to the advisory council. Section 406 sets forth the functions and membership of the advisory councils for the research institutes, with special provisions for the advisory councils of the National Cancer Institute (NCI) and the National Heart, Lung, and Blood Institute (NHLBI). Section 407 requires the institute Directors to prepare reports for inclusion in NIH Directors' biennial report. Section 408 extends the authorization of appropriations for the National Cancer Institute and the National Heart, Lung, and Blood Institute for three fiscal years as follows: for NCI programs other than Cancer Control Programs, $1,194,000,000 for

FY86, $1,270,000,000 for FY87, and $1,344,000,000 for FY88; for Cancer Control Programs, $68,000,000 for FY86, $74,000,000 for FY87, and $80,000,000 for FY88; for NHLBI programs other than prevention and control programs, $809,000,000 for FY86 $871,000,000 for FY87, and $927,000,000 for FY88; for programs in heart, blood vessil, lung, and blood disease prevention and control, $82,000,000 for FY86, $90,000,000 for FY87, and $98,000,000 for FY88. This section also requires the Secretary to report to Congress the amount obligated for administrative expenses each fiscal year.

The new Part C of Title IV (Sec. 410–463) has twelve subparts, each setting forth specific provisions of a research institute.

Subpart 1 (Sec. 410–416) pertains to the National Cancer Institute. The various sections set forth the purpose of the Institute (Sec. 410); describe the National Cancer Program (Sec. 411), including the cancer control programs (Sec. 412) and the national cancer research and demonstration centers (Sec. 414); set forth the responsibilities of the NCI Director (Sec. 413); describe the makeup and function of the President's Cancer Panel (Sec. 415); and establish in NCI an Associate Director for Prevention (Sec. 416).

Subpart 2 (Sec. 418–424) pertains to the National Heart, Lung, and Blood Institute. The various sections set forth the purpose of the Institute (Sec. 418); describe the heart, blood vessel, lung, and blood disease prevention and control programs (Sec. 419), the information and education programs (Sec. 420), the National Heart, Blood Vessel, Lung, and Blood Diseases and Blood Resources Program (Sec. 421), the national research and demonstration centers for heart, blood vessel, lung, and blood diseases, sickle cell anemia, and blood resources (Sec. 422); establish the Interagency Technical Committee on Heart, Blood Vessel, Lung and Blood Diseases and Blood Resources (Sec. 432); and establish in NHLBI an Associate Director for Prevention (Sec. 424).

Subpart 3 (Sec. 426–433) pertains to the National Institute of Diabetes and Digestive and Kidney Diseases. The various sections set forth the purpose of the Institute (Sec. 426); provide for the establishment of the National Diabetes Data System, the National Diabetes Information Clearinghouse, the National Digestive Diseases Data System, the National Digestive Diseases Information Clearinghouse, the National Kidney and Urologic Diseases Data System, and the National Kidney and Urologic Diseases Information Clearingnouse (Sec. 427); provide for a Division Director for Diabetes, Endorcrinology, and Metabolic Diseases, a Division Director for Digestive Diseases and Nutrition, and a Divison Director for Kidney, Urologic, and Hematologic Diseases, and outline their responsibilities (Sec. 428); provide for the establishment of a Diabetes Mellitus Interagency Coordinating Committee, a Digestive Diseases Interagency Coordinating Committee, and a Kidney, Urologic, and Hematologic Diseases Coordinating Committee (Sec. 429); provide for the establishment of the National Diabetes Advisory Board, the National Digestive Diseases Advisory Board, and the National Kidney and Urologic Diseases Advisory Board, describe the membership and responsibilities of the Boards, and set their termination date at the end of FY88 (Sec. 430); provide for the development of centers for research and training in diabetes, digestive diseases, and kidney and urologic diseases (Sec. 431); provide for three sub-

committees within the Institute's advisory council (Sec. 432); and require the Institute Director to report on activities under the research plans for diabetes and digestive diseases (Sec. 433).

Subpart 4 (Sec.435–442) pertains to the National Institute of Arthritis and Musculoskeletal and Skin Diseases. The various sections set forth the purpose of the Institute (Sec. 435); provide for the development of a plan for a national arthritis and musculoskeletal disease program (Sec. 436); provide for programs for research and training in the diagnosis, prevention, and treatment of arthritis and musculoskeletal and skin diseases (Sec. 437); provide for the establishment of the National Arthritis and Musculoskeletal and Skin Diseases Data System and the National Arthritis and Musculoskeletal and Skin Disease Information Clearinghouse (Sec. 438); provide for the establishment of an Arthritis and Musculoskeletal Diseases Intergancy Coordinating Committee and a Skin Diseases Interagency Coordinating Committee, and require the Committees to submit annual reports on their activities (Sec. 439); provide for the support of arthritis and musculoskeletal diseases demonstration projects (Sec. 440); provide for the development, modernizaton, and operation of new and existing multipurpose centers for arthritis and musculoskeletal diseases (Sec. 441); provide for the establishment of the National Arthritis Advisory Board, and describe the membership and responsibilities of the Board (Sec. 442).

Subpart 5 (Sec. 443–445) pertains to the National Institute on Aging. It sets forth the purpose of the Institute (Sec. 443); lists special functions concerning the training of health personnel in the field of health care for the aged, the assessment of the impact of DHHS programs in aging, the conduct of public information education programs, and the making of grants for research of Alzheimer's disease (Sec. 444); and provides for grants to support centers for basic and clinical research on Alzheimer's disease (Sec. 445).

Subpart 6 (Sec. 446) sets forth the purpose of the National Institute of Allergy and Infectious Diseases.

Subpart 7 (Sec. 448–451) pertains to the National Institute of Child Health and Human Development. It sets forth the purpose of the Institute (Sec. 448); requires the support of research on sudden infant death syndrome and on mental retardation (Sec. 449 and 450); and establishes in the Institute the position of Associate Director for Prevention (Sec. 451).

Subpart 8 (Sec. 453) sets forth the purpose of the National Institute of Dental Research.

Subpart 9 (Sec. 445) sets forth the purpose of the National Eye Institute.

Subpart 10 (Sec. 457–459) pertains to the National Institute of Neurological and Communicative Disorders and Stroke. It sets forth the purpose of the Institute (Sec. 457) and requires support of research on spinal cord regeneration (Sec. 458) and on use of electrical stimulation, computers, and other forms of bioengineering to overcome paralysis of the extremities (Sec. 459).

Subpart 11 (Sec. 461) sets forth the purpose of the National Institute of General Medical Sciences.

Subpart 12 (Sec. 463) sets forth the purpose of the National Institute of Environmental Health Sciences.

The new Part D of Title IV (Sec. 467–480) pertains to the National Library of Medicine. Subpart 1—"General Provisions" establishes the Library and sets forth its purpose (Sec. 467); describes the functions of the Library, including management of its collections, provision of assistance and materials to researchers and other libraries, and establishment of regional medical libraries (Sec. 469); provides for and describes the membership and functions of the Library's Board of Regents (Sec. 469); and authorizes appropriations for buildings and facilities for the Library (Sec. 470). Subpart 2—"Financial Assistance" extends the authorization of appropriations for the grant programs under the Medical Library Assistance Act as follows; $12,000,000 for FY86, $13,000,000 for FY87, and $14,000,000 for FY88 (Sec. 472); defines the terms "medical library" and "sciences related to health" (Sec. 473); outlines the functions of the National Medical Libraries Assistance Advisory Board, which has the same membership as the Board of Regents (Sec. 474); provides for grants for training in medical library sciences (Sec. 475); provides for grants for special scientific projects and for research and development in medical library science and related fields (Sec. 476); provides for grants for establishing, expanding, and improving the basic resources of medical libraries and related instrumentalities (Sec. 477); provides for grants and contracts for establishment of regional libraries (Sec. 478); provides for financial support of biomedical scientific publications (Sec. 479); and specifies the record-keeping requirements for grant recipients.

The new Part E of Title IV (Sec. 482–483) sets forth the purposes of two other agencies of NIH, the Division of Research Resources (Sec. 482) and the John E. Fogarty International Center for Advanced Study in the Health Sciences (Sec. 483).

The new Part F of Title IV (Sec. 485–487) pertains to awards and training of biomedical and behavioral research personnel. Section 485 describes the National Research Service Awards (NRSA) program for research and training in biomedical and behavioral research at NIH and the Alcohol, Drug Abuse, and Mental Health Administration (ADAMHA). It specifies the application and award procedures, as well as the service obligation and payback requirements for NRSA recipients. It extends the authorization of appropriations for the NRSA program for three fiscal years as follows: $223,000,000 for FY86, $235,000,000 for FY87, and $245,000,000 for FY88. Finally, it specifies the proportions of appropriated funds to be allotted to different categories of awardees. Section 486 provides for Visiting Scientist Awards to outstanding scientists who agree to serve as visiting scientists at institutions of postsecondary education which have significant enrollments of disadvantaged students. Section 487 requires the Secretary to arrange for a study every five years which would: establish the Nation's overall need for biomedical and behavioral research personnel, including the subject areas and types of training needed; assess current training programs available through NIH, ADAMHA, and other programs for the training of such personnel; identify the kinds of research positions available for such personnel; determine whether the currently available training programs could replace those supported by NIH and ADAMHA; and determine how the training programs should be modified to meet the Nation's personnel needs. The Secretary is

directed to request the National Academy of Sciences to conduct each study.

The new Part G of Title IV (Sec. 489–497) details a number of general provisions respecting NIH research. Section 489 requires the establishment of Institutional Review Boards (IRBs) by each entity applying for Federal funds to conduct biomedical or behavioral research involving human subjects; provides for a DHHS program to give ethical guidance to research insititutions; and provides for the establishment of a process for NIH to respond to reports of violations of the rights of human research subjects. Section 490 directs the Secretary to require, by regulation, appropriate technical and scientific peer review of all extramural grants, contracts, and cooperative agreements administered through NIH. It also requires the NIH Director to establish procedures for periodic technical and scientific peer review of intramural research at NIH. Section 491 directs the Secretary to require, by regulation, that each entity receiving Federal funds for biomedical or behavioral research establish an administrative process to reveiw reports of scientific fraud in such research; it also requires the NIH Director to establish a process for NIH to respond to reports of scientific fraud in connection with federally-funded projects. Section 492 provides that, in the case of the appearance of a disease or disorder constituting a public health emergency, the Secretary shall expedite the review of research grants and contracts dealing with such a disease and is authorized to provide administrative supplemental increases in relevant existing grants and contracts. Section 493 requires the Secretary to establish guidelines for the proper care and treatment of animals used in biomedical and behavioral research supported by funds under this Act; requires that animal care committees be established at each entity that conducts such research involving animals; provides that applicants for NIH funds must certify that they meet the animal care guidelines and also provide a statement of the reasons for the use of animals in their research; and provides that the NIH Director may suspend or revoke a grant or contract if the Director determines that a research entity is in violation of the guidelines and has not taken corrective action even after notification. Section 494 specifies the use of appropriations under this title. Section 495 authorizes the Secretary to accept gifts for NIH. Section 496 prohibits the conduct or support of research or experimentation involving the use of any living human fetus ex utero, unless the research may directly benefit the health of that fetus, or the research is for the development of important biomedical knowledge unobtainable by other means and it will pose no added risk of suffering, injury, or death to the fetus. With respect to living human fetuses in utero, this section requires that the risk standard published in the Code of Federal Regulations be the same for fetuses which are intended to be aborted and fetuses which are intended to be carried to term. This section also directs that the Biomedical Ethics Advisory Committee (created by Section 11 of this bill) conduct a study of the nature, advisability, and biomedical and ethical implications of exercising any waiver of this risk standard; it also prohibits the Secretary from granting any such waiver for 36 months from the effective date of this section. The prohibition is to be repealed effective October 31, 1988. Section 497 reaf-

firms that Section 301 of the Public Health Service Act represents the general legislative authority for NIH programs, and that the Secretary's authority under Section 301 is not limited by the provisions of Title IV.

Section 3 of the bill makes technical and conforming amendments to various sections of the PHSA. The National Advisory Health Council established under section 217 of the PHSA is terminated. Sections 217, 222 and 301 of the PHSA are amended in several places by removing references to the National Advisory Health Council, and extraneous references to other NIH advisory councils. Parts I and J of Title III, concerning the National Library of Medicine and assistance to medical libraries, are repealed. Section 8(w) of the Orphan Drug Act, concerning support of comprehensive centers for sickle cell disease, is repealed. Section 506 of the PHSA, concerning peer review of ADAMHA grants and contracts, is amended to allow the Secretary to make grants and cooperative agreements of less than $50,000 without referral to the advisory council.

Section 4 of the bill requires the NIH Director, with the assistance of an interagency coordinating committee, to establish a plan for research into alternatives to the use of animals in biomedical and behavioral research. Methods to be explored include those which do not require the use of animals, or which reduce the number of animals needed, or which produce less pain and distress in animals than methods currently in use. The plan is to address the validity and reliability of the methods, the development of those found valid and reliable, and the training of scientists in the use of such methods. The plan is to be submitted by October 1, 1986.

Section 5 of the bill requires the Secretary to establish a Lupus Erythematosus Coordinating Committee to plan, develop, coordinate, and implement comprehensive Federal initiatives in research on lupus erythematosus. The Committee, composed of representatives from various Federal agencies, is to transmit a report of its activities within eighteen months, after which the Committee will terminate. The report is to describe existing federally-supported research projects on lupus erythematosus, including information on the nature, purpose, costs, and performer of each project.

Section 6 of the bill requires the Secretary to conduct a study of the National Research Service Awards (NRSA) program. It is to cover the effect of the service obligation requirement on the number and quality of individuals who apply for NRSAs, the effect of the payback requirement on the number of persons who engage in health research or training as a career, the number of persons who receive NRSAs and who engage in health research or training as a career, and the effectiveness of institutional grants in encouraging individuals to engage in health research and training as a career. The Secretary is to complete the study one year after the effective date of this Act and report the results to the Congress.

Section 7 of the bill requires the Secretary to establish an Interagency Committee on Spinal Cord Injury within the National Institute of Neurological and Communicative Disorders and Stroke. The Committee is to plan, develop, coordinate, and implement comprehensive Federal initiatives in research on spinal cord injury and re-

generation. The Committee, composed of representatives from various Federal agencies, is to transmit a report of its activities within eighteen months, after which the Committee will terminate. The report is to describe existing federally-supported research projects on spinal cord injury and regeneration, including information on the nature, purpose, costs, and performer of each project.

Section 8 of the bill requires the Secretary to conduct a study of the adequacy and availability of health care personnel to meet the needs of elderly Americans through the year 2020. The Secretary is to report the results of the study to Congress by March 1, 1986. The report is to contain recommendations on the number of physicians, dentists, and other health personnel needed for the elderly; the training needs of such personnel; and changes in medicare and other reimbursement programs necessary to support training of such personnel.

Section 9 of the bill requires the NIH Director to establish an Interagency Committee on Learning Disabilities, which is to review and assess Federal research priorities, activities, and findings regarding learning disabilities, including the role of central nervous system dysfunction in children. The Committee, composed of representatives from various Federal agencies, is to transmit a report of its activities within eighteen months, after which the Committee will terminate. The report is to discuss the population affected by learning disabilities, current research findings, and recommendations for increasing the effectiveness of research and for setting research priorities on learning disabilities.

Section 10 of the bill requires the Secretary to conduct an administrative review of the disease research programs of the National Institute of Diabetes and Digestive and Kidney Diseases to determine if any of such programs could be more effectively and efficiently managed by other national research institutes.

Section 11 of the bill amends Title III of the Public Health Service Act (as amended by section 3) by adding a new Part I—Biomedical Ethics (Sec. 381). The new Part establishes in the legislative branch of Government the Biomedical Ethics Board, consisting of six Senators and six Representatives. The Board is to study and report to the Congress on a continuing basis on the ethical issues arising from the delivery of health care and biomedical and behavioral research, including the protection of human subjects of such research and developments in genetic engineering which have implications for human genetic engineering. A report on genetic engineering developments is to be transmitted to the Congress within eighteen months after the appointment of the Committee. Annual reports are to be transmitted to Congress identifying other issues which would be appropriate subjects for study. To conduct the studies and make the reports, the Board is to appoint a fourteen-member Biomedical Ethics Advisory Committee, with representatives from a broad range of scientific and social disciplines. The Committee is authorized to employ staff and consultants, hold public hearings, request Federal agency personnel on detail, and request information from any Federal agency. Appropriations for the Board and the Committee are authorized as follows: $2,000,000 for FY86, $2,500,000 for FY87, and $3,000,000 for FY88.

Section 12 of the bill states that this Act and the amendments made by this Act are to take effect October 1, 1985.

XI. Changes in Existing Law

In compliance with rule XXVI, paragraph 12 of the Standard Rules of the Senate, the following provides a print of the statute or the part or section thereof to be amended or replaced (existing law proposed to be omitted is enclosed in black brackets, new matter is printed in italic, existing law in which no change is proposed is shown in roman):

Public Health Service Act

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TITLE II—ADMINISTRATION

PUBLIC HEALTH SERVICE

Sec. 201. * * *

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NATIONAL ADVISORY COUNCILS

Sec. 217. (a) The [National Advisory Health Council, the National Advisory Mental Health Council, the National Advisory Council on Alcohol Abuse and Alcoholism, and the National Advisory Dental Research Council] *National Advisory Mental Health Council and the National Advisory Council on Alcohol Abuse and Alcoholism* shall each consist of the Surgeon General, who shall be chairman, the chief medical officer of the Veterans' Administration or his representative and a medical officer designated by the Secretary of Defense, who shall be ex officio members; and twelve members appointed without regard to the civil service laws by the [Surgeon General with the approval of the Secretary of Health, Education, and Welfare] *Secretary.* The twelve appointed members of each such council shall be leaders in the fields of fundamental sciences, medical sciences, or public affairs, and six of such twelve shall be selected from among the leading medical or scientific authorities who, [in the case of the National Advisory Health Council, are skilled in the sciences related to health, and] in the case of [the National Advisory Mental Health Council, the National Advisory Council on Alcohol Abuse and Alcoholism, the National Advisory Heart Council, and the National Advisory Dental Research Council,] the *National Advisory Mental Health Council and the National Advisory Council on Alcohol Abuse and Alcoholism,* are outstanding in the study, diagnosis, or treatment of psychiatric disorders[, alcohol abuse and alcoholism, and dental diseases and conditions] *and alcohol abuse and alcoholism,* respectively. [In the case of the National Advisory Dental Research Council, four of such six shall be dentists.] In the case of the National Advisory Council on Alcohol Abuse and Alcoholism, the Secretary shall assure that its membership is broadly representative of experts in the fields of prevention, research, and treatment of alcohol abuse, alcoholism, and rehabilitation of alcohol abusers. Each appointed

member of each such council shall hold office for a term of four years, except that (1) any member appointed to fill a vacancy occurring prior to the expiration of the terms for which his predecessor was appointed shall be appointed for the remainder of such term; (2) the terms of the members (other than the members of the National Advisory Council on Alcohol Abuse and Alcoholism) first taking office after September 30, 1950, shall expire as follows: Three shall expire four years after such date, three shall expire three years after such date, three shall expire two years after such date, and three shall expire one year after such date, as designated by the Surgeon General at the time of appointment; and (3) the terms of the members of the National Council on Alcohol Abuse and Alcoholism first taking office after the date of enactment of this clause, shall expire as follows: Three shall expire four years after such date, three shall expire three years after such date, three shall expire two years after such date, and three shall expire one year after such date, as designated by the Secretary at the time of appointment. None of the appointed members shall be eligible for reappointment within one year after the end of his preceding term, but terms expiring prior to October 1, 1950, shall not be deemed "preceding terms" for the purposes of this sentence.

[(b) The National Advisory Health Council shall advise, consult with, and make recommendations to, the Surgeon General on matters relating to health activities and functions of the Service. The Surgeon General is authorized to utilize the services of any member or members of the Council, and where appropriate, any member or members of the national advisory councils or committees established under this Act on mental health, alcohol abuse and alcoholism, dental, rheumatism, arthritis, and metabolic diseases, neurological diseases and blindness, and other diseases, in connection with matters related to the work of the Service, for such periods, in addition to conference periods, as he may determine.]

[(c)](*b*) The National Advisory Mental Health Council shall advise, consult with, and make recommendations to the Surgeon General on matters relating to the activities and functions of the Service in the field of mental health. The Council is authorized (1) to review research projects or programs submitted to or inititated by it in the field of mental health and recommend to the Surgeon General, for prosecution under this Act, any such projects which it believes show promise of making valuable contributions to human knowledge with respect to the cause, prevention, or methods of diagnosis and treatment of psychiatric disorders; and (2) to collect information as to studies being carried on in the field of mental health and, with the approval of the Surgeon General, make available such information through the appropriate publications for the benefit of health and welfare agencies or organizations (public and private), physicians, or any other scientists, and for the information of the general public. The council is also authorized to recommend to the Surgeon General, for acceptance pursuant to section 2101 of this Act, conditional gifts for work in the field of mental health; and the Surgeon General shall recommend acceptance of any such gifts only after consultation with the Council.

[(d)](c) The National Advisory Council on Alcohol Abuse and Alcoholism shall advise, consult with, and make recommendations to, the Secretary on matters relating to the activities and functions of the Secretary in the field of alcohol abuse and alcoholism, including policies and priorities with respect to grants and contracts. The Council is authorized (1) to review research projects or programs submitted to or initiated by it in the field of alcohol abuse and alcoholism and recommended to the Secretary any such projects which it believes show promise of making valuable contributions to human knowledge with respect to the cause, prevention, or methods of diagnosis and treatment of alcohol abuse and alcoholism, and (2) to collect information as to studies being carried on in the field of alcohol abuse and alcoholism and, with the approval of the Secretary, make available such information through appropriate publications for the benefit of health and welfare agencies or organizations (public or private) or physicians or any other scientists, and for the information of the general public. The Council is also authorized to recommend to the Secretary, for acceptance pursuant to section 2101 of this Act, conditional gifts for work in the field of alcohol abuse and alcoholism; and the Secretary shall recommend acceptance of any such gifts only after consultation with the Council.

[(e)](d)(1) The National Advisory Council on Drug Abuse shall consist of the Secretary, who shall be Chairman, the chief medical officer of the Veterans' Administration or his representative, and a medical officer designated by the Secretary of Defense, who shall be ex officio members. In addition, the Council shall be composed of twelve members appointed by the Secretary without regard to the provisions of title 5, United States Code, governing appointments in the competitive service. The appointed members of the Council shall represent a broad range of interests, disciplines, and expertise in the drug area and shall be selected from outstanding professionals and para-professionals in the fields of medicine, education, science, the social sciences, and other related disciplines, who have been active in the areas of drug abuse prevention, treatment, rehabilitation, training, or research.

(2) The Council shall advise, consult with, and make recommendations to, the Secretary—

(A) concerning matters relating to the activities and functions of the Secretary in the field of drug abuse, including, but not limited to, the development of new programs and priorities, the efficient administration of programs, and the supplying of needed scientific and statistical data and program information to professionals, paraprofessionals, and the general public; and

(B) concerning policies and priorities respecting grants and contracts in the field of drug abuse.

[(g)](e)(1) Within 120 days of the date of the enactment of this subsection, the Secretary shall appoint and organize a National Advisory Council on Migrant Health (hereinafter in this subsection referred to as the Council) which shall advise, consult with, and make recommendations to, the Secretary on matters concerning the organization, operation, selection, and funding of migrant

health centers and other entities under grants and contracts under section 329.

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ADVISORY COUNCILS OR COMMITTEES

SEC. 222. (a) * * *

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(c) Upon appointment of any such council or committee, the [Surgeon General, with the approval of the Secretary, may transfer such of the functions of the National Advisory Health Council relating to grants-in-aid for research or training projects or programs in the areas or fields with which such council or committee is concerned as he determines to be appropriate] *Secretary may delegate to such council or committee such advisory functions relating to grants-in-aid for research or training projects or programs, in the areas or fields with which such council or committee is concerned, as the Secretary determines to be appropriate.*

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TITLE III—GENERAL POWERS AND DUTIES OF PUBLIC HEALTH SERVICE

PART A—RESEARCH AND INVESTIGATION

IN GENERAL

SEC. 301. (a) The Secretary shall conduct in the Service, and encourage, cooperate with, and render assistance to other appropriate public authorities, scientific institutions, and scientists in the conduct of, and promote the coordination of, research, investigations, experiments, demonstrations, and studies relating to the causes, diagnosis, treatment, control, and prevention of physical and mental diseases and impairments of man, including water purification, sewage treatment, and pollution of lakes and streams. In carrying out the foregoing the Secretary is authorized to—

(1) collect and make available through publications and other appropriate means, information as to, and the practical application of, such research and other activities;

(2) make available research facilities of the Service to appropriate public authorities, and to health officials and scientists engaged in special study;

(3) make grants-in-aid to universities, hospitals, laboratories, and other public or private institutions, and to individuals for such research projects [as are recommended by the National Advisory Health Council, or, with respect to cancer, recommended by the National Cancer Advisory Board, or, with respect to mental health, recommended by the National Advisory Mental Health Council, or with respect to heart, blood vessel, lung, and blood diseases and blood resources, recommended by the National Heart, Lung, and Blood Advisory Council, or, with respect to dental diseases and conditions, recommended by the National Advisory Dental Research Council, and in-

clude in the grants for any such project grants of penicillin and other antibiotic compounds for use in such project; and make, upon recommendation of the National Advisory Health Council, grants-in-aid to public or nonprofit universities, hospitals, laboratories, and other institutions for the general support of their research: *Provided*, That such uniform percentage, not to exceed 15 per centum, as the Secretary may determine, of the amounts provided for grants for research projects for any fiscal year through the appropriations for the National Institutes of Health may be transferred from such appropriations to a separate account to be available for such research grants-in-aid for such fiscal year] *as are recommended by the advisory council to the entity of the Department supporting such projects or, in the case of mental health projects, by the National Advisory Mental Health Council; and make, upon recommendation of the advisory council to the entity of the department involved or the National Advisory Mental Health Council, grants-in-aid to public or nonprofit universities, hospitals, laboratories, and other institutions for the general support of their research;*

* * * * * * *

(8) adopt, upon recommendations of the National Advisory Health Council, or with respect to cancer, upon recommendation of the National Cancer Advisory Board or with respect to mental health, upon [recommendation of the National Advisory Mental Health Council, or, with respect to heart, blood vessel, lung, and blood diseases and blood resources, upon recommendation of the National Heart, Lung, and Blood Advisory Council, or, with respect to dental diseases and conditions, upon recommendation of the National Advisory Dental Research Council, such additional means as he deems] *recommendations of the advisory councils to the entities of the department involved or, with respect to mental health, the National Advisory Mental Health Council, such additional means as the Secretary considers* necessary or appropriate to carry out the purposes of this section.

The Secretary may make available to individuals and entities, for biomedical and behavioral research, substances and living organisms. Such substances and organisms shall be made available under such terms and conditions (including payment for them) as the Secretary determines appropriate.

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[PART I—NATIONAL LIBRARY OF MEDICINE

[PURPOSE AND ESTABLISHMENT OF LIBRARY

[SEC. 381. In order to assist the advancement of medical and related sciences, and to aid the dissemination and exchange of scientific and other information important to the progress of medicine and to the public health, there is hereby established in the Public Health Service a National Library of Medicine (hereinafter referred to in this part as the "Library").

[FUNCTIONS OF THE LIBRARY

[SEC. 382. (a) The Secretary, through the Library and subject to the provisions of subsection (c), shall—

[(1) acquire and preserve books, periodicals, prints, films, recordings, and other library materials, pertinent to medicine;

[(2) organize the materials specified in clause (1) by appropriate cataloging, indexing, and bibliographical listing;

[(3) publish and make available the catalogs, indexes, and bibliographies referred to in clause (2);

[(4) make available, through loans, photographic or other copying procedures or otherwise, such materials in the Library as he deems appropriate;

[(5) provide reference and research assistance; and

[(6) engage in such other activities in furtherance of the purposes of this part as he deems appropriate and the Library's resources permit.

[(b) The Secretary may exchange, destroy, or otherwise dispose of any books, periodicals, films, and other library materials not needed for the permanent use of the Library.

[(c) The Secretary is authorized, after obtaining the advice and recommendations of the Board (established under section 383), to prescribe rules under which the Library will provide copies of its publications or materials, or will make available its facilities for research or its bibliographic, reference, or other services, to public and private agencies and organizations, institutions, and individuals. Such rules may provide for making available such publications, materials, facilities, or services (1) without charge as a public service, or (2) upon a loan, exchange, or charge basis, or (3) in appropriate circumstances, under contract arrangements made with a public or other nonprofit agency, organization, or institution.

[BOARD OF REGENTS

[SEC. 383. (a) There is hereby established in the Public Health Service a Board of Regents of the National Library of Medicine (referred to in this part as the "Board") consisting of the Surgeons General of the Public Health Service, the Army, the Navy, and the Air Force, the Chief Medical Director of the Department of Medicine and Surgery of the Veterans' Administration, the Assistant Director for Biological and Medical Sciences of the National Science Foundation, and the Librarian of Congress, all of whom shall be ex officio members and ten members appointed by the Secretary. The ten appointed members shall be selected from among leaders in the various fields of the fundamental sciences, medicine, dentistry, public health, hospital administration, pharmacology, or scientific or medical library work, or in public affairs. At least six of the appointed members shall be selected from among leaders in the fields of medical, dental, or public health research or education. The Board shall annually elect one of the appointed members to serve as Chairman until the next election. The Secretary shall designate a member of the Library staff to act as executive secretary of the Board.

[(b) It shall be the duty of the Board to advise, consult with, and make recommendations to the Secretary on important matters of

policy in regard to the Library, including such matters as the acquisition of materials for the Library, the scope, content and organization of the Library's services, and the rules under which its materials, publications, facilities, and services shall be made available to various kinds of users, and the Secretary shall include in his annual report to the Congress a statement covering the recommendations made by the Board and the disposition thereof. The Secretary is authorized to use the services of any member or members of the Board in connection with matters related to the work of the Library, for such periods, in addition to conference periods, as he may determine.

[(c) Each appointed member of the Board shall hold office for a term of four years, except that (A) any member appointed to fill a vacancy occurring prior to the expiration of the term for which his predecessor was appointed shall be appointed for the remainder of such term, and (B) the terms of the members first taking office after the date of enactment of this part shall expire as follows: three at the end of four years after such date, three at the end of three years after such date, two at the end of two years after such date, and two at the end of one year after such date, as designated by the Secretary at the time of appointment. None of the appointed members shall be eligible for reappointment within one year after the end of his preceding term.

[GIFTS TO LIBRARY

[SEC. 384. The provisions of section 2101 shall be applicable to the acceptance and administration of gifts made for the benefit of the Library or for carrying out any of its functions, and the Board shall make recommendations to the Secretary of Health, Education, and Welfare relating to establishment within the Library of suitable memorials to the donors.

[DEFINITIONS

[SEC. 385. For purposes of this part the terms "medicine" and "medical" shall, except when used in section 383, be understood to include preventive and therapeutic medicine, dentistry, pharmacy, hospitalization, nursing, public health, and the fundamental sciences related thereto, and other related fields of study, research, or activity.

[LIBRARY FACILITIES

[SEC. 386. There are hereby authorized to be appropriated sums sufficient for the erection and equipment of suitable and adequate buildings and facilities for use of the Library in carrying out the provisions of this part. The Administrator of General Services is authorized to acquire, by purchase, condemnation, donation, or otherwise, a suitable site or sites, selected by the Secretary in accordance with the direction of the Board, for such buildings and facilities and to erect thereon, furnish, and equip such buildings and facilities. The sums herein authorized to be appropriated shall include the cost of preparation of drawings and specifications, supervision of construction, and other administrative expenses incident

to the work. The Administrator of General Services shall prepare the plans and specifications, make all necessary contracts, and supervise construction.

[TRANSFER OF ARMED FORCES MEDICAL LIBRARY

[SEC. 387. All civilian personnel, equipment, library collections, other personal property, records, and unexpended balances of appropriations, allocations, and other funds (available or to be made available), which the Director of the Bureau of the Budget shall determine to relate primarily to the functions of the Armed Forces Medical Library, are hereby transferred to the Service for use in the administration and operation of this part. Such transfer of property, funds, and personnel, and the other provisions of this part, shall become effective on the first day, occurring not less than thirty days after the date of enactment of this part, which the Director of the Bureau of the Budget determines to be practicable.

[REGIONAL BRANCHES OF THE NATIONAL LIBRARY OF MEDICINE

[SEC. 388. (a) Whenever the Secretary, with the advice of the Board, determines that—

[(1) in any geographic area of the United States, there is no regional medical library adequate to serve such area;

[(2) under the criteria prescribed in section 397, there is a need for a regional medical library to serve such area; and

[(3) because there is located in such area no medical library which, under the provisions of section 397 can feasibly be developed into a regional medical library adequate to serve such area,

he is authorized to establish, as a branch of the National Library of Medicine, a regional medical library to serve the needs of such area.

[(b) For the purpose of establishing branches of the National Library of Medicine under this section, there are hereby authorized to be appropriated for each fiscal year, beginning with the fiscal year ending June 30, 1966, and ending with the fiscal year ending June 30, 1970, such sums, not to exceed $2,000,000 for any fiscal year, as may be necessary. Sums appropriated pursuant to this section for any fiscal year shall remain available until expended.

[PART J—ASSISTANCE TO MEDICAL LIBRARIES

[DECLARATION OF POLICY, STATEMENT OF PURPOSE, AND AUTHORIZATION OF APPROPRIATIONS

[SEC. 390. (a) The Congress hereby finds and declares that (1) the unprecedented expansion of knowledge in the health sciences within the past two decades has brought about a massive growth in the quantity, and major changes in the nature of, biomedical information, materials, and publications; (2) there has not been a corresponding growth in the facilities and techniques necessary adequately to coordinate and disseminate among health scientists and practitioners the ever-increasing volume of knowledge and information which has been developed in the health science field; (3) much of the value of the ever-increasing volume of knowledge and infor-

mation which has been, and continues to be, developed in the health science field will be lost unless proper measures are taken in the immediate future to develop facilities and techniques necessary to collect, preserve, store, process, retrieve, and facilitate the dissemination and utilization, of such knowledge and information.

[(b) It is therefore the policy of this part to—

[(1) assist in the training of medical librarians and other information specialists in the health sciences;

[(2) assist, through grants to physicians and other practitioners in the sciences related to health, to scientists, and to public or nonprofit private institutions on behalf of such physicians, other practitioners, and scientists, in the compilation of existing, and the creation of additional, written matter which will facilitate the distribution and utilization of knowledge and information relating to scientific, social, and cultural advancements in sciences related to health;

[(3) assist in the conduct of research, investigations, and demonstrations in the field of medical library science and related activities, and in the development of new techniques, systems, and equipment for processing, storing, retrieving, and distributing information in the sciences related to health;

[(4) assist in establishing, expanding, and improving the basic resources of medical libraries and related facilities;

[(5) assist in the development of a national system of regional medical libraries each of which would have facilities of sufficient depth and scope to supplement the services of other medical libraries within the region served by it; and

[(6) provide financial support to biomedical scientific publications.

[(c) For the purpose of grants and contracts under sections 393, 394, 395, 396, and 397, there are authorized to be appropriated $17,500,000 for the fiscal year ending June 30, 1975, $20,000,000 for the fiscal year ending June 30, 1976, $14,600,000 for the fiscal year ending September 30, 1978, $15,000,000 for the fiscal year ending September 30, 1979, $16,500,000 for the fiscal year ending September 30, 1980, $18,500,000 for the fiscal year ending September 30, 1981, and $7,500,000 for the fiscal year ending September 30, 1982.

[DEFINITIONS

[SEC. 391. As used in this part—

[(1) the term "sciences related to health" includes medicine, osteopathy, dentistry, and public health, and fundamental and applied sciences when related thereto;

[(2) the terms "National Medical Libraries Assistance Advisory Board" and "Board" mean the Board of Regents of the National Library of Medicine established under section 383(a) of this Act; and

[(3) the term "medical library" means a library related to the sciences related to health.

[NATIONAL MEDICAL LIBRARIES ASSISTANCE BOARD

[SEC. 392. (a) The Board of Regents of the National Library of Medicine established pursuant to section 383(a) shall, in addition to

its functions prescribed under section 383, constitute and serve as the National Medical Libraries Assistance Advisory Board (hereinafter in this part referred to as the "Board").

[(b) The Board shall advise and assist the Secretary in the preparation of general regulations and with respect to policy matters arising in the administration of this part.

[(c) The Secretary is authorized to use the services of any member or members of the Board, in connection with matters related to the administration of this part for such periods, in addition to conference periods, as he may determine.

[(d) Appointed members of the Board who are not otherwise in the employ of the United States, while attending conferences of the Board or otherwise serving at the request of the Secretary in connection with the administration of this part, shall be entitled to receive compensation, per diem in lieu of subsistence, and travel expenses in the same manner and under the same conditions as that prescribed under section 383(d) when attending conferences, traveling, or serving at the request of the Secretary in connection with the administration of part I.

[GRANTS FOR TRAINING IN MEDICAL LIBRARY SCIENCES

[SEC. 393. (a) To carry out the purposes of section 390(b)(1), the Secretary shall make grants—

[(1) to individuals to enable them to accept traineeships and fellowships leading to postbaccalaureate academic degrees in the field of medical library science, in related fields pertaining to sciences related to health, or in the field of the communication of information;

[(2) to individuals who are librarians or specialists in information on sciences relating to health, to enable them to undergo intensive training or retraining so as to attain greater competence in their occupations (including competence in the fields of automatic data processing and retrieval);

[(3) to assist appropriate public and private nonprofit institutions in developing, expanding, and improving, training programs in library science and the field of communications of information pertaining to sciences relating to health; and

[(4) to assist in the establishment of internship programs in established medical libraries meeting standards which the Secretary shall prescribe.

[(b) Payment pursuant to grants made under this section may be made in advance or by way of reimbursement and in such installments as the Secretary shall prescribe by regulations after consultation with the Board.

[ASSISTANCE FOR SPECIAL SCIENTIFIC PROJECTS, AND FOR RESEARCH AND DEVELOPMENT IN MEDICAL LIBRARY SCIENCE AND RELATED FIELDS

[SEC. 394. (a) To carry out the purposes of section 390(b)(2), the Secretary shall make grants to physicians and other practitioners in the sciences related to health, to scientists, and to public or nonprofit private institutions on behalf of such physicians, or other practitioners, and scientists for the compilation of existing, or writing of original, contributions relating to scientific, social, or cultur-

al, advancements in sciences related to health. In making such grants, the Secretary shall make appropriate arrangements whereby the facilities of the National Library of Medicine and the facilities of libraries of public and private nonprofit institutions of higher learning may be made available in connection with the projects for which such grants are made.

[(b) To carry out the purposes of section 390(b)(3) the Secretary shall make grants to appropriate public or private nonprofit institutions and enter into contracts with appropriate persons, for purposes of carrying out projects of research, investigations, and demonstrations in the field of medical library science and related activities and for the development of new techniques, systems and equipment, for processing, storing, retrieving, and distributing information pertaining to sciences related to health.

[(c) Payment pursuant to grants made under this section may be in advance or by way of reimbursement and in such installments as the Secretary shall prescribe by regulations after consultation with the Board.

[GRANTS FOR ESTABLISHING, EXPANDING, AND IMPROVING THE BASIC RESOURCES OF MEDICAL LIBRARIES AND RELATED INSTRUMENTALITIES

[SEC. 395. (a) To carry out the purposes of section 390(b)(4), the Secretary shall make grants of money, materials, or both, to public or private nonprofit medical libraries and related scientific communication instrumentalities for the purpose of establishing, expanding, and improving their basic medical library or related resources. The uses for which grants so made may be employed include, but are not limited to, the following: (1) acquisition of books, journals, photographs, motion picture and other films, and other similar materials, (2) cataloging, binding, and other services and procedures for processing library resource materials for use by those who are served by the library or related instrumentality, and (3) acquisition of duplication devices, facsimile equipment, film projectors, recording equipment and other equipment to facilitate the use of the resources of the library or related instrumentality by those who are served by it, and (4) introduction of new technologies in medical librarianship.

[(b)(1) The amount of any grant under this section to any medical library or related instrumentality shall be determined by the Secretary on the basis of the scope of library or related services provided by such library or instrumentality in relation to the population and purposes served by it. In making a determination of the scope of services served by any medical library or related instrumentality, the Secretary shall take into account the following factors—

[(A) the number of graduate and undergraduate students making use of the resources of such library or instrumentality;

[(B) the number of physicians and other practitioners in the sciences related to health utilizing the resources of such library or instrumentality;

[(C) the type of supportive staffs, if any, available to such library or instrumentality;

[(D) the type, size, and qualifications of the faculty of any school with which such library or instrumentality is affiliated;

[(E) the staff of any hospital or hospitals or of any clinic or clinics with which such library or instrumentality is affiliated; and

[(F) the geographic area served by such library or instrumentality and the availability, within such area, of medical library or related services provided by other libraries or related instrumentalities.

[(2) In no case shall any grant under this section to a medical library or related instrumentality for any fiscal year exceed $200,000; and grants to such medical libraries or related instrumentalities shall be in such amounts as the Secretary may by regulation prescribe with a view to assuring adequate continuing financial support for such libraries or instrumentalities from other sources during and after the period for which Federal assistance is provided.

[GRANTS AND CONTRACTS FOR ESTABLISHMENT OF REGIONAL MEDICAL LIBRARIES

[SEC. 396. (a) To carry out the purposes of section 390(b)(5), the Secretary, with the advice of the Board, shall make grants to existing public or private nonprofit medical libraries so as to enable each of them to serve as the regional medical library for the geographical area in which it is located.

[(b) The uses for which grants made under this section may be employed include, but are not limited to, the following—

[(1) acquisition of books, journals, and other similar materials;

[(2) cataloging, binding, and other procedures for processing library resource materials for use by those who are served by the library;

[(3) acquisition of duplicating devices and other equipment to facilitate the use of the resources of the library by those who are served by it;

[(4) acquisition of mechanisms and employment of personnel for the speedy transmission of materials from the regional library to local libraries in the geographic area served by the regional library; and

[(5) planning for services and activities under this section.

[(c)(1) Grants under this section shall be made only to medical libraries which agree (A) to modify and increase their library resources, and to supplement the resources of cooperating libraries in the region, so as to be able to provide adequate supportive services to all libraries in the region as well as to individual users of library services, (B) to provide free loan services to qualified users, and make available photoduplicated or facsimile copies of biomedical materials which qualified requesters may retain.

[(2) The Secretary, in awarding grants under this section, shall give priority to medical libraries having the greatest potential of fulfilling the needs for regional medical libraries. In determining the priority to be assigned to any medical library, he shall consider—

[(A) the adequacy of the library (in terms of collections, personnel, equipment, and other facilities) as a basis for a regional medical library; and

[(B) the size and nature of the population to be served in the region in which the library is located.

[(d) Grants under this section for basic resource materials to a library may not exceed 50 per centum of the library's annual operating expense (exclusive of Federal financial assistance under this part) for the preceding year; or in case of the first year in which the library receives a grant under this section for basic resource materials, 50 per centum of its average annual operating expenses over the past three years (or if it had been in operation for less than three years, its annual operating expenses determined by the Secretary in accordance with regulations prescribed by him).

[(e) Payment pursuant to grants made under this section may be made in advance or by way of reimbursement and in such installment as the Secretary shall prescribe by regulations after consultation with the Board.

[(f) The Secretary may also carry out the purposes of this section through contracts, and such contracts shall be subject to the same limitations as are provided in this section for grants.

[FINANCIAL SUPPORT OF BIOMEDICAL SCIENTIFIC PUBLICATIONS

[SEC. 397. (a) To carry out the purposes of section 390(b)(6), the Secretary, with the advice of the Board, shall make grants to, and enter into appropriate contracts with, public or private nonprofit institutions of higher education and individual scientists for the purpose of supporting biomedical scientific publications of a nonprofit nature and to procure the compilation, writing, editing, and publication of reviews, abstracts, indices, handbooks, bibliographies, and related matter pertaining to scientific works and scientific developments.

[(b) Grants under this section in support of any single periodical publication may not be made for more than three years, except in those cases in which the Secretary determines that further support is necessary to carry out the purposes of this section.

[(c) Payment pursuant to grants made under this section may be made in advance or by way of reimbursement and in such installments as the Secretary shall prescribe by regulations after consultation with the Board.

[CONTINUING AVAILABILITY OF APPROPRIATED FUNDS

[SEC. 398. Funds appropriated to carry out any of the purposes of this part for any fiscal year shall remain available for such purposes for the fiscal year immediately following the fiscal year for which they were appropriated.

[RECORDS AND AUDIT

SEC. 399. (a) Each recipient of a grant under this part shall keep such records as the Secretary shall prescribe, including records which fully disclose the amount and disposition by such recipient of the proceeds of such grant, the total cost of the project or under-

taking in connection with which such grant is given or used, and the amount of that portion of the cost of the project or undertaking supplied by other sources, and such other records as will facilitate an effective audit.

[(b) The Secretary of Health, Education, and Welfare and the Comptroller General of the United States, or any of their duly authorized representatives, shall have access for the purpose of audit and examination to any books, documents, papers, and records of such recipients that are pertinent to any grant received under the provisions of this part.]

Part I—Biomedical Ethics

Sec. 381. (a) There is established in the legislative branch of the Government the Biomedical Ethics Board (hereinafter referred to as the "Board").

(b)(1) The Board shall consist of twelve members as follows:

(A) Six Members of the Senate appointed as follows: Three members appointed by the Majority Leader of the Senate from the majority party and three members appointed by the Minority Leader from the minority party.

(B) Six Members of the House of Representatives appointed by the Speaker of the House of Representatives, three from the majority party and three from the minority party.

(2) The term of office of a member of the Board shall expire when the member leaves the office of Senator or Representative, as the case may be, or upon the expiration of eight years after the date of the member's appointment to the Board, whichever occurs first.

(3) Vacancies in the membership of the Board shall not affect the power of the remaining members to execute the functions of the Board and shall be filled in the same manner as in the case of the original appointment.

(4) The Board shall select a chairman and a vice chairman from among its members at the beginning of each Congress. The vice chairman shall act as chairman in the absence of the chairman or in the event of the incapacity of the chairman. The chairmanship and vice chairmanship shall alternate between the Senate and the House of Representatives with each Congress. The chairman during each even-numbered Congress shall be selected by the Members of the House of Representatives on the Board from among their number. The vice chairman during each Congress shall be chosen in the same manner from that House of Congress other than the House of Congress of which the chairman is a Member.

(5) The Board shall meet once every three months unless such meeting is dispensed with by the chairman, and may meet at any time upon the request of four or more members of the Board or upon the call of the chairman.

(c)(1) The Board shall study and report to the Congress on a continuing basis on the ethical issues arising from the delivery of health care and biomedical and behavioral research, including the protection of human subjects of such research and developments in genetic engineering (including activities in recombinant DNA technology) which have implications for human genetic engineering.

(2)(A) Except as provided in subparagraph (B), an annual report shall be transmitted to the Congress identifying the issues which were the subject of the study conducted under paragraph (1) and identifying areas, programs, and practices of medicine and biomedical and behavioral research which have significant ethical implications and which would be appropriate subjects for study.

(B) A report on research and developments in genetic engineering (including activities in recombinant DNA technology) which have implications for human genetic engineering shall be transmitted to the Congress not later than eighteen months after the appointment of the Committee under subsection (d).

(d)(1) To conduct the studies and make the reports required by subsection (c), the Board shall appoint a Biomedical Ethics Advisory Committee (hereinafter referred to as the 'Committee'). The Committee shall consist of fourteen members as follows:

(A) Four of the members shall be appointed by the Board from individuals who are distinguished in biomedical or behavioral research.

(B) Three of the members shall be appointed by the Board from individuals who are distinguished in the practice of medicine or otherwise distinguished in the provision of health care.

(C) Five of the members shall be appointed by the Board from individuals who are distinguished in one or more of the fields of ethics, theology, law, the natural sciences (other than the biomedical or behavioral sciences), the social sciences, the humanities, health administration, government, and public affairs.

(D) Two of the members shall be appointed by the Board from individuals who are representatives of citizens with an interest in biomedical ethics but who possess no specific expertise.

(2)(A) The Committee, by majority vote, shall elect from its members a chairman and a vice chairman and appoint an executive director who shall serve for such time and under such conditions as the Committee may prescribe. In the absence of the chairman, or in the event of the incapacity of the chairman, the vice chairman shall act as chairman.

(B) The term of office of each member of the Committee shall be four years, except that any such member appointed to fill a vacancy occurring prior to the expiration of the term for which such member's predecessor was appointed shall be appointed for the remainder of such term. Terms of the members shall be staggered so as to establish a rotating membership.

(C) The members of the Committee shall receive no pay for their services as members of the Committee, but shall be allowed necessary travel expenses (or, in the alternative, mileage for use of privately owned vehicles and a per diem in lieu of subsistence at not to exceed the rate prescribed in sections 5702 and 5704 of title 5, United States Code) and other necessary expenses incurred by them in the performance of duties as a member of the Committee, without regard to the provisions of subchapter 1 of chapter 57 and section 5731 of title 5, United States Code, and regulations promulgated thereunder.

(D) The executive director of the Committee, with the approval of the Committee, may employ such staff and consultants as necessary to prepare studies and reports for the Committee.

(3)(A) The Committee may, for the purpose of carrying out its functions, hold such public hearings, sit and act at such times and places, and take such testimony, as the Committee considers appropriate.

(B) Upon request of the Committee, the head of any Federal agency is authorized to detail, on a reimbursable basis, any of the personnel of such agency to the Committee to assist the Committee in carrying out its functions.

(C) The Committee may secure directly from any department or agency of the United States information necessary to enable it to carry out its functions. Upon request of the chairman of the Committee, the head of such department or agency shall furnish such information to the Committee.

(D) The Committee may accept, use, and dispose of gifts or donations or services or property.

(E) The Committee may use the United States mails in the same manner and under the same conditions as other departments and agencies of the United States.

(e) To enable the Board and the Committee to carry out their functions there are authorized to be appropriated $2,000,000 for fiscal year 1986, $2,500,000 for fiscal year 1987, and $3,000,000 for fiscal year 1988.

TITLE IV—NATIONAL RESEARCH INSTITUTES

[PART A—NATIONAL CANCER INSTITUTE

[A DIVISION OF THE NATIONAL INSTITUTES OF HEALTH

[SEC. 400. The National Cancer Institute (in this part referred to as the "Institute") is a division of the National Institutes of Health.

[CANCER RESEARCH AND OTHER ACTIVITIES

[SEC. 401. (a) In carrying out the purposes of section 301 with respect to cancer, the Secretary, through the Institute and in cooperation with the National Cancer Advisory Board, shall—

[(1) conduct, assist, and foster research, investigations, experiments, and studies relating to the cause, prevention, and methods of diagnosis and treatment of cancer;

[(2) promote the coordination of research conducted by the Institute and similar research conducted by other agencies and organizations and by individuals;

[(3) provide clinical training and instruction in technical matters relating to the diagnosis and treatment of cancer;

[(4) secure for the Institute consultation services and advice of cancer experts from the United States and abroad;

[(5) cooperate with State health agencies in the prevention, control, and eradication of cancer; and

[(6) procure, use, and lend radium as provided in subsection (b).

[(b) In carrying out subsection (a), all appropriate provisions of section 301 shall be applicable to the authority of the Secretary, and the Secretary is authorized—

[(1) to purchase radium, from time to time and without regard to section 3709 of the Revised Statutes, and to make such radium available for the purposes of this part, both to the Service and by loan to other agencies and institutions for such consideration and subject to such conditions as he may prescribe; and

[(2) to provide the necessary facilities where training and instruction may be given in all technical matters relating to the diagnosis and treatment of cancer to persons found by the Secretary to have proper technical qualifications and designated by him for such training or instruction and to fix and pay them a per diem allowance during such training or instruction.

[NATIONAL CANCER PROGRAM

[SEC. 402. The National Cancer Program shall consist of (1) an expanded, intensifed, and coordinated cancer research program encompassing the research programs conducted and supported by the Institute and the related research programs of the other research institutes and including an expanded and intensified research program for the prevention of cancer caused by occupational or environmental exposure to carcinogens, and (2) the other programs and activities of the Institute.

[CANCER CONTROL PROGRAMS

[SEC. 403. The Director of the Institute shall establish and support demonstration, education, and other programs for the detection, diagnosis, prevention, and treatment of cancer and for rehabilitation and counseling respecting cancer. Programs established and supported under this section shall include—

[(1) locally initiated education and demonstration programs (and regional networks of such programs) to transmit research results and to disseminate information respecting the detection, diagnosis, prevention, and treatment of cancer and rehabilitation and counseling respecting cancer to physicians and other health professionals who provide care to individuals who have cancer;

[(2) the demonstration of and the education of health professionals in—

[(A) effective methods for the early detection of cancer and the identification of individuals with a high risk of developing cancer, and

[(B) improved methods of patient referral to appropriate centers for early diagnosis and treatment of cancer; and

[(3) the demonstration of new methods for the dissemination of information to the general public concerning the early detection and treatment of cancer and information concerning unapproved and ineffective methods, drugs, and devices for the diagnosis, prevention, treatment, and control of cancer.

[DUTIES AND FUNCTIONS OF THE DIRECTOR

[SEC. 404. (a) The Director of the Institute in carrying out the National Cancer Program shall—

[(1) collect, analyze, and disseminate information (including information respecting nutrition programs for cancer patients and the relationship between nutrition and cancer) useful in the prevention, diagnosis, and treatment of cancer, including the establishment of an international cancer research data bank to collect, catalog, store, and disseminate insofar as feasible the results of cancer research undertaken in any country for the use of any person involved in cancer research in any country;

[(2) establish or support the large-scale production or distribution of specialized biological materials and other therapeutic substances for research and set standards of safety and care for persons using such materials;

[(3) support research in the cancer field outside the United States by highly qualified foreign nationals which research can be expected to inure to the benefit of the American people; support collaborative research involving American and foreign participants; and support the training of American scientists abroad and foreign scientists in the United States;

[(4) support appropriate programs of education (including continuing education) and training in fundamental sciences and clinical disciplines for investigators, physicians, and allied health professionals for participation in clinical programs relating to cancer, including the use of training stipends, fellowships, and career awards;

[(5) expeditiously utilize existing research facilities and personnel of the National Institutes of Health for accelerated exploration of opportunities in areas of special promise;

[(6) encourage and coordinate cancer research by industrial concerns where such concerns evidence a particular capability for such research;

[(7) provide and contract for a program to disseminate and interpret, on a current basis, for practitioners and other health professionals, scientists, and the general public, scientific and other information respecting the cause, prevention, diagnosis, and treatment of cancer;

[(8)(A) prepare and submit, directly to the President for review and transmittal to Congress, an annual budget estimate (including an estimate of the number and type of personnel needs for the National Cancer Institute) for the National Cancer Program, after reasonable opportunity for comment (but without change) by the Secretary, the Director of the National Institutes of Health, and the National Cancer Advisory Board; and (B) receive from the President and the Office of Management and Budget directly all funds appropriated by Congress for obligation and expenditure by the Institute; and

[(9) as soon as practicable after the end of each fiscal year, prepare in consultation with the National Cancer Advisory Board and submit to the Secretary, for simultaneous transmittal, not later than November 30 of each year, to the President and to the Congress, a report on the activities, progress, and accomplishments under the National Cancer Program during the preceding fiscal year, which shall include a report on the progress, activities, and accomplishments of, and expenditures

for, the information services of the Program, and a plan for the Program during the next five years.

[(b) The Director of the Institute (after consultation with the National Cancer Advisory Board) in carrying out his functions in administering the National Cancer Program and without regard to any other provision of this Act is authorized—

[(1) to obtain (in accordance with section 3109 of title 5, United States Code and if authorized by the National Cancer Advisory Board, but without regard to the limitation in such section on the number of days or the period of such service) the services of not more than one hundred and fifty-one experts or consultants who have scientific or professional qualifications;

[(2) to acquire, construct, improve, repair, operate, and maintain cancer centers, laboratories, research, and other necessary facilities and equipment, and related accommodations as may be necessary, and such other real or personal property (including patents) as the Director deems necessary to acquire, without regard to the Act of March 3, 1877 (40 U.S.C. 34), by lease or otherwise through the Administrator of General Services, buildings or parts of buildings in the District of Columbia or communities located adjacent to the District of Columbia for the use of the Institute for a period not to exceed ten years;

[(3) to appoint one or more advisory committees composed of such private citizens and officials of Federal, State, and local governments as he deems desirable to advise him with respect to his functions;

[(4) to utilize, with their consent, the services, equipment, personnel, information, and facilities of other Federal, State, or local public agencies, with or without reimbursement therefor;

[(5) to accept voluntary and uncompensated services;

[(6) to accept unconditional gifts, or donations of services, money, or property, real, personal, or mixed, tangible or intangible;

[(7) to enter into such contracts, leases, cooperative agreements, or other transactions, without regard to sections 3648 and 3709 of the Revised Statutes of the United States (31 U.S.C. 529, 41 U.S.C. 5), as may be necessary in the conduct of his functions, with any public agency, or with any person, firm, association, corporation, or educational institution;

[(8) to take necessary action to insure that all channels for the dissemination and exchange of scientific knowledge and information are maintained between the Institute and the other scientific, medical, and biomedical disciplines and organizations nationally and internationally;

[(9) to award grants for new construction as well as alterations and renovations for improvement of basic research laboratory facilities, including those related to biohazard control, as deemed necessary for the National Cancer Program; and

[(10) to call special meetings to the National Cancer Advisory Board at such times and in such places as the Director deems necessary in order to consult with, obtain advice from, or to secure the approval of projects, programs, or other ac-

tions to be undertaken without delay in order to gain maximum benefit from a new scientific or technical finding.

[SCIENTIFIC REVIEW

[SEC. 405. (a) The Director of the Institute shall, by regulation, provide for proper scientific review of all research grants and programs over which he has authority (1) by utilizing, to the maximum extent possible, appropriate peer review groups established within the National Institutes of Health and composed principally of non-Federal scientists and other experts in the scientific and disease fields, and (2) when appropriate, by establishing, with the approval of the National Cancer Advisory Board and the Director of the National Institutes of Health, other formal peer review groups as may be required.

[(b) Under procedures approved by the Director of the National Institutes of Health, the Director of the National Cancer Institute may approve grants under this Act for cancer research or training—

[(1) if the direct costs of such research and training do not exceed $35,000, but only after appropriate review for scientific merit, and

[(2) if the direct costs of such research and training exceed $35,000, but only after appropriate review for scientific merit and recommendation for approval by the National Cancer Advisory Board under section 407(b)(3).

[NATIONAL CANCER RESEARCH AND DEMONSTRATION CENTERS

[SEC. 406. (a) The Director of the Institute is authorized to provide for the establishment of new centers for basic and clinical research into, training in, and demonstration of, advanced diagnostic, prevention, and treatment methods for cancer. Such centers may be supported under subsection (b) or under any other applicable provision of law.

[(b) The Director of the Institute, under policies established by the Director of the National Institutes of Health and after consultation with the National Cancer Advisory Board, is authorized to enter into cooperative agreements with public or private nonprofit agencies or institutions to pay all or part of the cost of planning, establishing, or strengthening, and providing basic operating support for existing or new centers (including, but not limited to, centers established under subsection (a)) for basic and clinical research into, training in, and demonstration of advanced diagnostic, prevention, and treatment methods for cancer. Federal payments under this subsection in support of such cooperative agreements may be used for (1) construction (notwithstanding any limitation under section 477), (2) staffing and other basic operating costs, including such patient care costs as are required for research, (3) clinical training (including clinical training for allied health professionals, continuing education for health professionals and allied health professions personnel, and information programs for the public respecting cancer, and (4) demonstration purposes. The aggregate of payments (other than payments for construction) made to any center in support of such an agreement for its costs (other

than indirect costs) described in the first sentence may not exceed $5,000,000 in any fiscal year, except that if in any fiscal year there is an increase, as reflected in the Consumer Price Index published by the Bureau of Labor Statistics, in the cost of a center for which payments may be made under such an agreement, the aggregate of payments in such year for such center may exceed $5,000,000 to include such increase and any such increase in any preceding fiscal year for which payments were made to such center under such an agreement to the extent that such increase resulted in payments in excess of $5,000,000. As used in this section, the term "construction" does not include the acquisition of land, and the term "training" does not include research training for which fellowship support may be provided under section 472. Support of a center under this section may be for a period of not to exceed three years and may be extended by the Director of the Institute for additional periods of not more than three years each, after review of the operations of such center by an appropriate scientific review group established by the Director of the Institute.

[NATIONAL CANCER ADVISORY BOARD

[SEC. 407. (a)(1) There is established in the Institute a National Cancer Advisory Board (hereinafter in this section referred to as the "Board") to be composed of twenty-nine members as follows:

[(A) The Secretary, the Director of the Office of Science and Technology Policy, the Director of the National Institutes of Health, the chief medical officer of the Veterans' Administration, the Director of the National Institute for Occupational Safety and Health, the Director of the National Institute of Environmental Health Sciences, the Secretary of Labor, the Commissioner of the Food and Drug Administration, the Administrator of the Environmental Protection Agency, the Chairman of the Consumer Product Safety Commission (or their designees), and a medical officer designated by the Secretary of Defense shall be ex officio members of the Board.

[(B) Eighteen members appointed by the President.

Not more than twelve of the appointed members of the Board shall be scientists or physicians, not more than eight of the appointed members shall be representatives from the general public, and not less than five of the appointed members shall be individuals knowledgeable in environmental carcinogenesis (including carcinogenesis involving occupational and dietary factors). The scientists and physicians appointed to the Board shall be appointed from persons who are among the leading scientific or medical authorities outstanding in the study, diagnosis, or treatment of cancer or in fields related thereto, and at least two of the physicians appointed to the Board shall be physicians primarily involved in treating individuals who have cancer. Each appointed member of the Board shall be appointed from among persons who by virtue of their training, experience, and background are especially qualified to appraise the programs of the Institute. The ex officio members of the Board shall be nonvoting members.

[(2)(A) Appointed members shall be appointed for six-year terms, except that of the members first appointed six shall be appointed

for a term of two years, and six shall be appointed for a term of four years, as designated by the President at the time of appointment.

[(B) Any member appointed to fill a vacancy occurring prior to expiration of the term for which his predecessor was appointed shall serve only for the remainder of such term. Appointed members shall be eligible for reappointment and may serve after the expiration of their terms until their successors have taken office.

[(C) A vacancy in the Board shall not affect its activities, and twelve members thereof shall constitute a quorum.

[(3) The President shall designate one of the appointed members to serve as Chairman for a term of two years.

[(4) The Board shall meet at the call of the Director of the Institute or the Chairman, but not less often than four times a year and shall advise and assist the Director of the Institute with respect to the National Cancer Program.

[(5) The Director of the Institute shall designate a member of the staff of the Institute to act as Executive Secretary of the Board.

[(6) The Board may hold such hearings, take such testimony, and sit and act at such times and places as the Board deems advisable to investigate programs and activities of the National Cancer Program.

[(7) The Board shall submit a report to the Secretary for simultaneous transmittal by the Secretary, not later than November 30 of each year, to the President and the Congress, on the progress during the preceding fiscal year of the National Cancer Program toward the accomplishment of its objectives.

[(8) Members of the Board who are not officers or employees of the United States shall receive for each day they are engaged in the performance of the duties of the Board compensation at rates not to exceed the daily equivalent of the annual rate in effect for GS–18 of the General Schedule, including traveltime; and all members while so serving away from their homes or regular places of business, may be allowed travel expenses, including per diem in lieu of subsistence, in the same manner as such expenses are authorized by section 5703, title 5, United States Code, for persons in the Government service employed intermittently.

[(9) The Director of the Institute shall make available to the Board such staff, information, and other assistance as it may require to carry out its activities.

[(b) The Board is authorized—

[(1) to review research projects or programs conducted or authorized to be conducted under section 401 relating to the study of the cause, prevention, or methods of diagnosis and treatment of cancer, and recommend to the Secretary any such projects which it believes show promise of making valuable contributions to human knowledge with respect to the cause, prevention, or methods of diagnosis and treatment of cancer;

[(2) to collect information as to studies which are being carried on in the United States or any other country as to the cause, prevention, and methods of diagnosis and treatment of cancer, by correspondence or by personal investigation of such studies, and with the approval of the Secretary make available such information through the appropriate publications for the

benefit of health agencies and organizations (public or private), physicians, or any other scientists, and for the information of the general public;

[(3) to review applications for grants for research projects relating to cancer and to recommend to the Director for approval under section 405(b)(2) those applications which show promise of making valuable contributions to human knowledge with respect to the cause or prevention of cancer or to methods of diagnosis or treatment of cancer;

[(4) to recommend to the Secretary for acceptance conditional gifts pursuant to section 501 of this Act; and

[(5) to make recommendations to the Secretary with respect to carrying out the provisions of this part.

[PRESIDENT'S CANCER PANEL

[SEC. 408. (a)(1) There is established the President's Cancer Panel (hereinafter in this section referred to as the "Panel") which shall be composed of three persons appointed by the President, who by virtue of their training, experience, and background are exceptionally qualified to appraise the National Cancer Program. At least two of the members of the Panel shall be distinguished scientists or physicians.

[(2)(A) Members of the Panel shall be appointed for three-year terms, except that (i) in the case of two of the members first appointed, one shall be appointed for a term of one year and one shall be appointed for a term of two years, as designated by the President at the time of appointment, and (ii) any member appointed to fill a vacancy occurring prior to the expiration of the term for which his predecessor was appointed shall be appointed only for the remainder of such term.

[(B) The President shall designate one of the members to serve as Chairman for a term of one year.

[(C) Members of the Panel shall each be entitled to receive the daily equivalent of the annual rate of basic pay in effect for grade GS–18 of the General Schedule for each day (including traveltime) during which they are engaged in the actual performance of duties vested in the Panel, and shall be allowed travel expenses (including a per diem allowance) under section 5703(b) of title 5, United States Code.

[(3) The Panel shall meet at the call of the Chairman, but not less often than four times a year. A transcript shall be kept of the proceedings of each meeting of the Panel, and the Chairman shall make such transcript available to the public.

[(b) The Panel shall monitor the development and execution of the National Cancer Program, and shall report directly to the President. Any delays or blockages in rapid execution of the Program shall immediately be brought to the attention of the President. The Panel shall submit to the President periodic progress reports on the Program and annually an evaluation of the efficacy of the Program and suggestions for improvements, and shall submit such other reports as the President shall direct.

[GIFTS

[SEC. 409. The Secretary shall recommend acceptance of conditional gifts pursuant to section 501 for study, investigation, or research into the cause, prevention, and methods of diagnosis and treatment of cancer, or for the acquisition of real property or the erection, equipment, or maintenance of premises, buildings, or equipment, of the Institute, only after consultation with the National Cancer Advisory Board. Donations of $50,000 or over in aid of research under this part may be acknowledged by the establishment within the Institute of suitable memorials to the donors.

[AUTHORIZATION OF APPROPRIATIONS

[SEC. 410. (a) For the purpose of carrying out this part (other than section 403), there are authorized to be appropriated $400,000,000 for the fiscal year ending June 30, 1972; $500,000,000 for the fiscal year ending June 30, 1973; $600,000,000 for the fiscal year ending June 30, 1974; $750,000,000 for the fiscal year ending June 30, 1975; $830,000,000 for the fiscal year ending June 30, 1976; $985,000,000 for the fiscal year ending September 30, 1977; $923,590,000 for the fiscal year ending September 30, 1978; $924,500,000 for the fiscal year ending September 30, 1979; $927,000,000 for the fiscal year ending September 30, 1980; $1,015,700,000 for the fiscal year ending September 30, 1981; and $1,109,000,000 for the fiscal year ending September 30, 1982.

[(b) There are authorized to be appropriated to carry out section 403, $20,000,000 for the fiscal year ending June 30, 1972; $30,000,000 for the fiscal year ending June 30, 1973; $40,000,000 for the fiscal year ending June 30, 1974; $53,500,000 for the fiscal year ending June 30, 1975; $68,500,000 for the fiscal year ending June 30, 1976; $88,500,000 for the fiscal year ending September 30, 1977; $84,560,000 for the fiscal year ending September 30, 1978; $90,500,000 for the fiscal year ending September 30, 1979; $103,000,000 for the fiscal year ending September 30, 1980; $112,900,000 for the fiscal year ending September 30, 1981; and $123,200,000 for the fiscal year ending September 30, 1982.

[(c) The authority of the Secretary to enter into any contract for the conduct of a program under section 404(a)(7) shall be effective for any fiscal year only to such extent or in such amounts as are provided in advance in appropriation Acts.

[PART B—NATIONAL HEART, LUNG, AND BLOOD INSTITUTE

[ESTABLISHMENT OF INSTITUTE

[SEC. 411. There is hereby established in the Public Health Service a National Heart, Lung, and Blood Institute (hereafter in this part referred to as the "Institute").

[RESEARCH AND TRAINING IN DISEASES OF THE HEART, BLOOD VESSELS, LUNG, AND BLOOD AND IN THE MANAGEMENT OF BLOOD RESOURCES

[SEC. 412. In carrying out the purposes of section 301 with respect to heart, blood vessel, lung, and blood diseases and with respect to the use of blood and blood products and the management

of blood resources the Secretary through the Institute and in cooperation with the National Heart, Lung, and Blood Advisory Council (hereinafter in this part referred to as the "Council"), shall—

[(1) conduct, assist, and foster researches, investigations, experiments, and demonstrations relating to the cause, prevention, and methods of diagnosis and treatment of heart, blood vessel, lung, and blood diseases and to the use of blood and blood products and the management of blood resources;

[(2) promote the coordination of research and control programs conducted by the Institute, and similar programs conducted by other agencies, organizations, and individuals;

[(3) make available research facilities of the Service to appropriate public authorities, and to health officials and scientists engaged in special studies related to the purposes of this part;

[(4) make grants-in-aid to universities, hospitals, laboratories, and other public or private agencies and institutions, and to individuals for such research projects relating to heart, blood vessel, lung, and blood diseases and to the use of blood and blood products and the management of blood resources are recommended by the Council, including grants to such agencies and institutions for the construction, acquisition, leasing, equipment, and maintenance of such hospital, clinic, laboratory, and related facilities, and for the care of such patients therein, as are necessary for such research;

[(5) establish an information center on research, prevention, diagnosis, and treatment of heart, blood vessel, lung, and blood diseases and on the use of blood and blood products and the management of blood resources, and collect and make available on a timely basis, through publications and other appropriate means, information as to, and the practical application of, research and other activities carried on pursuant to this part;

[(6) secure from time to time, and for such periods as he deems advisable, the assistance and advice of persons from the United States or abroad who are experts in the field of heart, blood vessel, lung, and blood diseases and the management of blood resources;

[(7) in accordance with regulations and from funds appropriated or donated for the purpose, provide clinical training and instruction and establish and maintain clinical traineeships, in the Institute and elsewhere in matters relating to the diagnosis, prevention, and treatment of heart, blood vessel, lung, and blood diseases and to the use of blood and blood products and the management of blood resources with such stipends and allowances (including travel and subsistence expenses) for trainees as he may deem necessary, the number of persons receiving such training and instruction, and the number of persons holding such traineeships, to be fixed by the Council, and, in addition, provide for such training, instruction, and traineeships through grants, upon recommendation of the Council, to public and other nonprofit institutions.

[NATIONAL HEART, BLOOD VESSEL, LUNG, AND BLOOD DISEASES AND BLOOD RESOURCES PROGRAM

[SEC. 413. (a) The Director of the Institute, with the advice of the Council, shall develop a plan for a National Heart, Blood Vessel, Lung, and Blood Diseases and Blood Resources Program (hereafter in this part referred to as the "Program") to expand, intensify, and coordinate the activities of the Institute respecting heart, blood vessel, lung, and blood diseases and blood resources (including its activities under section 412) and shall carry out the Program in accordance with such plan. The Program shall be coordinated with the other research institutes of the National Institutes of Health to the extent that they have responsibilities respecting such diseases and shall provide for—

[(1) investigation into the epidemiology, etiology, and prevention of all forms and aspects of heart, blood vessel, lung, and blood diseases, including investigations into the social, environmental, behavioral, nutritional, biological, and genetic determinants and influences involved in the epidemiology, etiology, and prevention of such diseases;

[(2) studies and research into the basic biological processes and mechanisms involved in the underlying normal and abnormal heart, blood vessel, lung, and blood phenomena;

[(3) research into the development, trial, and evaluation of techniques, drugs, and devices (including computers) used in, and approaches to, the diagnosis, treatment (including emergency medical service), and prevention of heart, blood vessel, lung, and blood diseases and the rehabilitation of patients suffering from such diseases;

[(4) establishment of programs that will focus and apply scientific and technological efforts involving biological, physical, and engineering sciences to all facets of heart, blood vessel, lung, and blood diseases with emphasis on refinement, development, and evaluation of technological devices that will assist, replace, or monitor vital organs and improve instrumentation for detection, diagnosis, and treatment of those diseases;

[(5) establishment of programs for the conduct and direction of field studies, large-scale testing and evaluation, and demonstration of preventive, diagnostic, therapeutic, and rehabilitative approaches to, and emergency medical services for, such diseases;

[(6) studies and research into blood diseases and blood, and into the use of blood for clinical purposes and all aspects of the management of its resources in this country, including the collection, preservation, fractionalization, and distribution of it and its products;

[(7) the education and training of scientists, clinicians, and educators, in fields and specialties (including computer sciences) requisite to the conduct of clinical programs respecting heart, blood vessel, lung, and blood diseases and blood resources;

[(8) public and professional education relating to all aspects of such diseases and the use of blood and blood products and the management of blood resources;

[(9) establishment of programs for study and research into heart, blood vessel, lung, and blood diseases of children (including cystic fibrosis, hyaline membrane, and hemolytic and hemophilic diseases) and for the development and demonstration of diagnostic, treatment, and preventive approaches to these diseases; and

[(10) establishment of programs for study, research, development, demonstrations and evaluation of emergency medical services for people who become critically ill in connection with heart, blood vessel, lung, or blood diseases, which programs shall include programs for (A) the training of paraprofessionals in (i) emergency treatment procedures, and (ii) utilization and operation of emergency medical equipment, (B) the development and operation of (i) mobile critical care units (including helicopters and other airborne units where appropriate), (ii) radio, telecommunications, and other means of communications, and (iii) electronic monitoring systems, and (C) the coordination with other community services and agencies in the joint use of all forms of emergency vehicles, communications systems, and other appropriate services.

The Program shall give special emphasis to the continued development in the Institute of programs relating to atherosclerosis, hypertension, thrombosis, and congenital abnormalities of the blood vessels as causes of stroke, and to effective coordination of such programs with related stroke programs in the National Institute of Neurological Diseases and Stroke.

[(b)(1) The plan required by subsection (a) of this section shall (A) be developed within one hundred and eighty days after the effective date of this section, (B) be transmitted to the Congress, and (C) set out the Institute's staff requirements to carry out the Program and recommendations for appropriations for the Program.

[(2) The Director of the Institute shall, as soon as practicable after the end of each fiscal year, prepare in consultation with the Council and submit a report to the Secretary, for simultaneous transmittal by the Secretary, not later than November 30 of each year, to the President and to the Congress, on the activities, progress, and accomplishments under the Program during the preceding fiscal year and a plan for the Program during the next five years. Each such plan shall contain (A) an estimate of the number and type of personnel which will be required by the Institute to carry out the Program during the five years with respect to which the plan is submitted, and (B) recommendations for appropriations to carry out the Program during such five years.

[(c) In carrying out the Program, the Director of the Institute, under policies established by the Director of the National Institutes of Health and after consultations with the Council and without regard to any other provision of this Act, may—

[(1) if authorized by the Council, obtain (in accordance with section 3109 of title 5, United States Code, but without regard to the limitation in such section on the number of days or the period of such service) the services of not more than one hundred experts or consultants who have scientific or professional qualifications;

[(2) acquire, construct, improve, repair, operate, alter, renovate, and maintain heart, blood vessel, lung, and blood disease and blood resource laboratory, research, training, and other necessary facilities and equipment, and related accommodations as may be necessary, and such other real or personal property (including patents) as the Director deems necessary; and acquire, without regard to the Act of March 3, 1877 (40 U.S.C. 34), by lease or otherwise, through the Administrator of General Services, buildings or parts of buildings in the District of Columbia or communities located adjacent to the District of Columbia for the use of the Institute for a period not to exceed ten years; and

[(3) enter into such contracts, leases, cooperative agreements, or other transactions, without regard to sections 3648 and 3709 of the Revised Statutes of the United States (31 U.S.C. 529, 41 U.S.C. 5), as may be necessary in the conduct of his functions, with any public agency, or with any person, firm, association, corporation, or educational institution.

[(d) There shall be in the Institute an Assistant Director for Prevention, Education, and Control who shall be appointed by the Director of the Institute. The Director of the Institute, acting through the Assistant Director for Prevention, Education, and Control shall conduct a program to provide on a timely basis the public and the health professions with health information with regard to cardiovascular and, blood and pulmonary diseases and blood resources. In the conduct of such program, special emphasis shall be placed upon dissemination of information regarding diet and nutrition, environmental pollutants, exercise, stress, hypertension, cigarette smoking, weight control, and other factors affecting the prevention of arteriosclerosis and other cardiovascular diseases and of pulmonary and blood diseases.

[HEART, BLOOD VESSEL, LUNG, AND BLOOD DISEASE PREVENTION AND CONTROL PROGRAMS

[SEC. 414. (a) The Director of the Institute, under policies established by the Director of the National Institutes of Health and after consultation with the Council, shall establish programs as necessary for cooperation with other Federal health agencies, State, local, and regional public health agencies, and nonprofit private health agencies in the diagnosis, prevention, and treatment (including the provision of emergency medical services) of heart, blood vessel, lung, and blood diseases, appropriately emphasizing the prevention, diagnosis, and treatment of such diseases of children.

[(b) There is authorized to be appropriated to carry out this section $25,000,000 for the fiscal year ending June 30, 1973, $35,000,000 for the fiscal year ending June 30, 1974, $45,000,000 for the fiscal year ending June 30, 1975, $10,000,000 for fiscal year 1976, $30,000,000 for the fiscal year ending September 30, 1977, $30,000,000 for the fiscal year ending September 30, 1978, $40,000,000 for the fiscal year ending September 30, 1979, $45,000,000 for the fiscal year ending September 30, 1980,

$49,300,000 for the fiscal year ending September 30, 1981, and $53,800,000 for the fiscal year ending September 30, 1982.

NATIONAL RESEARCH AND DEMONSTRATION CENTERS FOR HEART, BLOOD VESSEL, LUNG, AND BLOOD DISEASES AND BLOOD RESOURCES

[SEC. 415. (a)(1) The Director of the Institute may provide for the development of—

[(A) ten new centers for basic and clinical research into, training in, and demonstration of, advanced diagnostic, prevention, and treatment methods (including methods of providing emergency medical services) for heart and blood vessel diseases,

[(B) ten new centers for basic and clinical research into, training in, and demonstration of, advanced diagnostic, prevention, and treatment methods (including methods of providing emergency medical services) for lung diseases (including bronchitis, emphysema, asthma, cystic fibrosis, and other lung diseases of children), and

[(C) ten new centers for basic and clinical research into, training in, and demonstration of, advanced diagnostic, prevention, and treatment methods (including methods of providing emergency medical services) for blood diseases and research into blood, in the use of blood products and in the management of blood resources.

[(2) The centers developed under paragraph (1) shall, in addition to being utilized for research, training, and demonstrations, be utilized for the following prevention programs for cardiovascular, pulmonary, and blood diseases:

[(A) Programs to develop improved methods of detecting individuals with a high risk of developing cardiovascular, pulmonary, and blood diseases.

[(B) Programs to develop improved methods of intervention against those factors which cause individuals to have a high risk of developing such diseases.

[(C) Programs to develop health professions and allied health professions personnel highly skilled in the prevention of such diseases.

[(D) Programs to develop improved methods of providing emergency medical services for persons with such diseases.

[(E) Programs of continuing education for health and allied health professionals in the diagnosis, prevention, and treatment of such diseases and information programs for the public respecting the prevention and early diagnosis and treatment of such diseases.

[(3) Centers developed under this subsection may be supported under subsection (b) or under any other applicable provision of law. The research, training, and demonstration activities carried out through any such center may relate to any one or more of the diseases referred to in paragraph (1) of this subsection.

[(b) The Director of the Institute, under policies established by the Director of the National Institutes of Health and after consultation with the Council, may enter into cooperative agreements with public or nonprofit private agencies or institutions to pay all

or part of the cost of planning, establishing, or strengthening, and providing basic operating support for, existing or new centers (including centers established under subsection (a)) for basic or clinical research into, training in, and demonstration of, the management of blood resources and advanced diagnostic, prevention, and treatment methods for heart, blood vessel, lung, or blood diseases. Funds paid to centers under cooperative agreements under this subsection may be used for—

[(1) construction, notwithstanding section 477,

[(2) staffing and other basic operating costs, including such patient care costs as are required for research,

[(3) training, including training for allied health professions personnel, and

[(4) demonstration purposes.

The aggregate of payments (other than payments for construction) made to any center under such an agreement for its costs (other than indirect costs) described in the first sentence may not exceed $5,000,000 in any fiscal year, except that if in any fiscal year there is an increase, as reflected in the Consumer Price Index published by the Bureau of Labor Statistics, in the costs of a center for which payments may be made under such an agreement, the aggregate of payments in such year for such center may exceed $5,000,000 to include such increase and any such increase in any preceding fiscal year for which payments were made to such center under such an agreement to the extent that such increase resulted in payments in excess of $5,000,000. Support of a center under this subsection may be for a period of not to exceed five years and may be extended by the Director of the Institute for additional periods of not more than five years each, after review of the operations of such center by an appropriate scientific review group established by the Director. As used in this section, the term "construction" does not include the acquisition of land; and the term "training" does not include research training for which fellowship support may be provided under section 472.

[INTERAGENCY TECHNICAL COMMITTEE

[SEC. 416. (a) The Secretary shall establish an Interagency Technical Committee on Heart, Blood Vessel, Lung and Blood Diseases and Blood Resources which shall be responsible for coordinating those aspects of all Federal health programs and activities relating to heart, blood vessel, lung, and blood diseases and to blood resources to assure the adequacy and technical soundness of such programs and activities and to provide for the full communication and exchange of information necessary to maintain adequate coordination of such programs and activities.

[(b) The Director of the Institute shall serve as Chairman of the Committee and the Committee shall include representation from all Federal departments and agencies whose programs involve health functions or responsibilities as determined by the Secretary.

[NATIONAL HEART, LUNG, AND BLOOD ADVISORY COUNCIL

[SEC. 417. (a) There is established in the Institute a National Heart, Lung, and Blood Advisory Council to be composed of twenty-three members as follows:

[(1) The Secretary, the Director of the National Institutes of Health, the Director of the Office of Science and Technology Policy, and the chief medical officer of the Veterans' Administration (or their designees), and a medical officer designated by the Secretary of Defense, shall be ex officio members of the Council.

[(2) Eighteen members appointed by the Secretary.

Eleven of the appointed members shall be selected from among the leading medical or scientific authorities who are skilled in the sciences relating to diseases of the heart, blood vessels, lungs, and blood; two of the appointed members shall be selected from persons enrolled in residency programs providing training in heart, blood vessel, lung, or blood diseases; and five of the appointed members shall be selected from members of the general public who are leaders in the fields of fundamental or medical sciences or in public affairs.

[(b)(1) Each appointed member of the Council shall be appointed for a term of four years, except that—

[(A) any member appointed to fill a vacancy occurring prior to the expiration of the term for which his predecessor was appointed shall be appointed for the remainder of such term; and

[(B) of the members first appointed after the effective date of this section, five shall be appointed for a term of four years, five shall be appointed for a term of three years, five shall be appointed for a term of two years, and three shall be appointed for a term of one year, as designated by the Secretary at the time of appointment.

Appointed members may serve after the expiration of their terms until their successors have taken office.

[(2) A vacancy in the Council shall not affect its activities, and twelve members of the Council shall constitute a quorum.

[(3) The Council shall supersede the existing National Advisory Heart Council appointed under section 217, and the appointed members of the National Advisory Heart Council serving on the effective date of this section shall serve as additional members of the National Heart, Lung, and Blood Advisory Council for the duration of their terms then existing, or for such shorter time as the Secretary may prescribe.

[(4) Members of the Council who are not officers or employees of the United States shall receive for each day they are engaged in the performance of the functions of the Council compensation at rates not to exceed the daily equivalent of the annual rate in effect for grade GS–18 of the General Schedule, including traveltime; and all members while so serving away from their homes or regular places of business, may be allowed travel expenses, including per diem in lieu of subsistence, in the same manner as such expenses are authorized by section 5703 of title 5, United States Code, for persons in the Government service employed intermittently.

[(c) The Secretary (or his designee) shall be the Chairman of the Council.

[(d) The Director of the Institute shall (1) designate a member of the staff of the Institute to act as Executive Secretary of the Council, and (2) make available to the Council such staff, information, and other assistance as it may require to carry out its functions.

[(e) The Council shall meet at the call of the Chairman, but not less often than four times a year. 418

[FUNCTIONS OF THE COUNCIL

[SEC. 418. (a) The Council is authorized to—

[(1) review research projects or programs submitted to or initiated by it relating to the study of the cause, prevention, or methods of diagnosis or treatment of heart, blood vessel, lung, and blood diseases and to the use of blood and blood products and the management of blood resources, and certify approval to the Secretary, for prosecution under section 412, any such projects which it believes show promise of making valuable contributions to human knowledge with respect to the cause, prevention, or methods of diagnosis or treatment of heart, blood vessel, lung, and blood diseases and to the use of blood products and the management of blood resources;

[(2) review applications from any university, hospital, laboratory, or other institution or agency, whether public or private, or from individuals, for grants-in-aid for research projects relating to heart, blood vessel, lung, and blood diseases and to the use of blood and blood products and the management of blood resources, and certify to the Secretary its approval of grants-in-aid in the cases of such projects which show promise of making valuable contributions to human knowledge with respect to the cause, prevention, or methods of diagnosis or treatment of heart, blood vessel, lung, and blood disease;

[(3) review applications from any public or other nonprofit institution for grants-in-aid for training, instruction, and traineeships in matters relating to the diagnosis, prevention, and treatment of heart, blood vessel, lung, and blood diseases and to the use of blood and blood products and the management of blood resources, and certify to the Secretary its approval of such applications for grants-in-aid as it determines will best carry out the purposes of this act;

[(4) recommend to the Secretary (A) areas of research in heart, blood vessels, lung, and blood diseases and in the use of blood and blood products and the management of blood resources which it determines should be supported by the awarding of contracts in order to best carry out the purposes of this part, and (B) the percentage of the budget of the Institute which should be expended for such contracts;

[(5) collect information as to studies which are being carried on in the United States or any other country as to the cause, prevention, or methods of diagnosis or treatment of heart, blood vessel, lung, and blood diseases and to the use of blood and blood products and the management of blood resources, by correspondence or by personal investigation of such studies,

and with the approval of the Secretary make available such information through appropriate publications for the benefit of health and welfare agencies and organization (public or private), physicians, or any other scientists, and for the information of the general public;

[(6) recommend to the Secretary for acceptance conditional gifts pursuant to section 501 for carrying out the purposes of this part; and

[(7) advise, consult with, and make recommendations to the Secretary, the Director of the National Institutes of Health, and the Director of the National Heart, Lung, and Blood Institute with respect to carrying out the provisions of this part.

[(b)(1) The Council shall advise and assist the Director of the Institute with respect to the Program established under section 413. The Council may hold such hearings, take such testimony, and sit and act at such times and places, as the Council deems advisable to investigate programs and activities of the Program.

[(2) The Council shall submit a report to the Secretary for simultaneous transmittal by the Secretary, not later than November 30 of each year, to the President and to the Congress on the progress of the Program toward the accomplishment of its objective during the preceding fiscal year.

[ADMINISTRATION

[SEC. 419A. (a) In carrying out the provisions of section 412 all appropriate provisions of section 301 shall be applicable to the authority of the Secretary, and except as provided in subsection (c), grants-in-aid for heart, blood vessel, lung, and blood disease research and training projects and projects with respect to the use of blood and blood products and the management of blood resources shall be made only after review and recommendation of the Council.

[(b) The Secretary may, in accordance with section 501, accept conditional gifts for study, investigation, or research into the cause, prevention, or methods of diagnosis or treatment of heart, blood vessel, lung, and blood diseases and into the use of blood and blood products and the management of blood resources, or for the acquisition of grounds or for the erection, equipment, or maintenance of premises, buildings or equipment of the Institute. Donations of $50,000 or over for carrying out the purposes of this part may be acknowledged by the establishment within the Institute of suitable memorials to the donors.

[(c) Under procedures approved by the Director of the National Institutes of Health, the Director of the National Heart, Lung, and Blood Institute may approve grants under this Act for research and training in heart, blood vessel, lung, and blood diseases and for research and training in the use of blood and blood products and the management of blood resources—

[(1) if the direct costs of such research and training do not exceed $35,000, but only after appropriate review for scientific merit but without review and recommendation by the Council, and

[(2) if the direct costs of such research and training exceed $35,000, but only after appropriate review for scientific merit and recommendation for approval by the Council.

[AUTHORIZATION OF APPROPRIATIONS

[SEC. 419B. For the purpose of carrying out this part (other than section 414), there is authorized to be appropriated $375,000,000 for the fiscal year ending June 30, 1973, $425,000,000 for the fiscal year ending June 30, 1974, $475,000,000 for the fiscal year ending June 30, 1975, $339,000,000 for fiscal year 1976, $373,000,000 for the fiscal year ending September 30, 1977, $426,320,000 for the fiscal year ending September 30, 1978, $470,000,000 for the fiscal year ending September 30, 1979, $515,000,000 for the fiscal year ending September 30, 1980, $564,300,000 for the fiscal year ending September 30, 1981, and $616,100,000 for the fiscal year ending September 30, 1982. Of the sums appropriated under this section for any fiscal year, not less than 15 per centum of such sums shall be reserved for programs under this part respecting diseases of the lung and not less than 15 per centum of such sums shall be reserved for programs under this part for programs respecting blood diseases and blood resources.

[PART C—NATIONAL INSTITUTE OF DENTAL RESEARCH

[ESTABLISHMENT OF INSTITUTE

[SEC. 421. There is hereby established in the Public Health Service a National Institute of Dental Research (hereafter in this part referred to as the "Institute").

[DENTAL DISEASE RESEARCH AND TRAINING

[SEC. 422. In carrying out the purposes of section 301 with respect to dental diseases and conditions the Surgeon General, through the Institute and in cooperation with the National Advisory Dental Research Council (hereafter in this part referred to as the "Council") shall—

[(a) conduct, assist, and foster researches, investigations, experiments, and studies relating to the cause, prevention, and methods of diagnosis and treatment of dental diseases and conditions;

[(b) promote the coordination of researches conducted by the Institute, and similar researches conducted by other agencies, organizations, and individuals;

[(c) secure for the Institute consultation services and advice of persons from the United States or abroad who are experts in the field of dental diseases and conditions;

[(d) cooperate with State health agencies in the prevention and control of dental diseases and conditions; and

[(e) provide clinical training and instruction and establish and maintain clinical traineeships, in the Institute and elsewhere in matters relating to the diagnosis, prevention, and treatment of dental diseases and conditions with such stipends and allowances (including travel and subsistence expenses) for trainees as he may deem necessary, the number of persons re-

ceiving such training and instruction, and the number of persons holding such traineeships, to be fixed by the Council, and, in addition, provide for such training, instruction, and traineeships through grants, upon recommendations of the Council, to public and other nonprofit institutions.

[ADMINISTRATION

[SEC. 423. (a) In carrying out the provisions of section 422 all appropriate provisions of section 301 shall be applicable to the authority of the Surgeon General, and grants-in-aid for dental research and training projects shall be made only after review and recommendation of the Council made pursuant to section 424.

[(b) The Surgeon General shall recommend to the Secretary acceptance of conditional gifts, pursuant to section 501, for study, investigation, or research into the cause, prevention, or methods of diagnosis or treatment of dental diseases and conditions, or for the acquisition of grounds or for the erection, equipment, or maintenance of premises, buildings, or equipment of the Institute. Donations of $50,000 or over for carrying out the purposes of this part may be acknowledged by the establishment within the Institute of suitable memorials to the donors.

[FUNCTIONS OF THE COUNCIL

[SEC. 424. The Council is authorized to—

[(a) review research projects or programs submitted to or initiated by it relating to the study of the cause, prevention, or methods of diagnosis and treatment of dental diseases and conditions, and certify approval to the Surgeon General, for prosecution under section 422(a) hereof, of any such projects which it believes show promise of making valuable contributions to human knowledge with respect to the cause, prevention, or methods of diagnosis and treatment of dental diseases and conditions;

[(b) collect information as to studies which are being carried on in the United States or any other country as to the cause, prevention, or methods of diagnosis or treatment of dental diseases and conditions, by correspondence or by personal investigation of such studies, and with the approval of the Surgeon General make available such information through appropriate publications for the benefit of health agencies and organizations (public or private), physicians, dentists, or any other scientists, and for the information of the general public;

[(c) review applications from any university, hospital, laboratory, or other institution, whether public or private, or from individuals, for grants-in-aid for research projects relating to dental diseases and conditions, and certify to the Surgeon General its approval of grants-in-aid in the cases of such projects which show promise of making valuable contributions to human knowledge with respect to the cause, prevention, or methods of diagnosis or treatment of dental diseases and conditions;

[(d) recommend to the Surgeon General for acceptance conditional gifts pursuant to section 501 for carrying out the purposes of this part;

[(e) make recommendations to the Surgeon General with respect to carrying out the provisions of this part; and

[(f) review applications from any public or other nonprofit institution for grants-in-aid for training, instruction, and traineeships in matters relating to the diagnosis, prevention, and treatment of dental diseases and conditions, and certify to the Surgeon General its approval of such applications for grants-in-aid as it determines will best carry out the purposes of this Act.

[PART D—NATIONAL INSTITUTE OF ARTHRITIS, DIABETES, AND DIGESTIVE AND KIDNEY DISEASES, NATIONAL INSTITUTE OF NEUROLOGICAL DISEASES AND STROKE, AND OTHER INSTITUTES

[ESTABLISHMENT OF INSTITUTES

[SEC. 431. (a) The Surgeon General shall establish in the Public Health Service an institute for research on arthritis, rheumatism, and metabolic diseases,[1] and an institute for research on neurological diseases (including epilepsy, cerebral palsy, and multiple sclerosis) and blindness, and he shall also establish a national advisory council or committee for each such institute to advise, consult with, and make recommendations to him with respect to the activities of the institute with which each council or committee is concerned.

[(b) The Surgeon General is authorized with the approval of the Secretary to establish in the Public Health Service one or more additional institutes to conduct and support scientific research and professional training relating to the cause, prevention, and methods of diagnosis and treatment of other particular diseases or groups of diseases (including poliomyelitis and leprosy) whenever the Surgeon General determines that such action is necessary to effectuate fully the purposes of section 301 with respect to such disease or diseases. Any institute established pursuant to this subsection may in like manner be abolished and its functions transferred elsewhere in the Public Health Service upon a finding by the Surgeon General that a separate institute is no longer required for such purposes. In lieu of the establishment pursuant to this subsection of an additional institute with respect to any disease or diseases, the Surgeon General may expand the functions of any institute established under subsection (a) of this section or under any other provision of this Act so as to include functions with respect to such disease or diseases and to terminate such expansion and transfer the functions given such institute elsewhere in the Service upon a finding by the Surgeon General that such expansion is no longer necessary. In the case of any such expansion of an existing institute, the Surgeon General may change the title thereof so as to reflect its new functions.

[[1] See section 434 which designates this research institute as the National Institute of Arthritis, Metabolism, and Digestive Diseases.

[ESTABLISHMENT OF NATIONAL ADVISORY COUNCILS

[SEC. 432. (a) The Surgeon General is also authorized with the approval of the Secretary to establish additional national advisory councils or committees to advise, consult with, and make recommendations to the Surgeon General on matters relating to the activities of any institute established under subsection (b) of section 431, or relating to the conduct and support of research and training in such disease or group of diseases (except a disease or group of diseases for which an institute is established under any provision of this title other than section 431(b)) as he may designate. Any such council, and each of the two councils or committees established under section 431(a), shall consist of the Surgeon General, who shall be chairman, the chief medical officer of the Veterans' Administration or his representative and a medical officer designated by the Secretary of Defense, who shall be ex officio members, and of twelve members appointed without regard to the civil service laws by the Surgeon General with the approval of the Secretary. The twelve appointed members shall be leaders in the field of fundamental sciences, medical sciences, education, or public affairs, and six of such twelve shall be selected from leading medical or scientific authorities who are outstanding in the study, diagnosis, or treatment of the disease or diseases to which the activities of the institute are directed. Each appointed member of the council shall hold office for a term of four years except that any member appointed to fill a vacancy occurring prior to the expiration of the term for which his predecessor was appointed shall be appointed for the remainder of such term and except that, of the members first appointed, three shall hold office for a term of three years, three shall hold office for a term of two years, and three shall hold office for a term of one year, as designated by the Surgeon General at the time of appointment. None of such twelve members shall be eligible for reappointment until a year has elapsed since the end of his preceding term.

[(b) In lieu of appointment of an additional advisory council or committee upon the establishment pursuant to subsection (b) of section 431 of an additional institute or upon expansion pursuant to such subsection of the functions of an institute, the Surgeon General may expand the functions of an advisory council or committee, established under section 431(a) of any other provisions of this Act so as to include functions with respect to the particular disease or diseases to which the activities of the additional institute or the expanded activities of the existing institute are directed. In the case of any such expansion of an existing council or committee, the membership thereof representing persons outstanding in activities with which the council or committee is concerned may be changed or increased so as to include some persons outstanding in the new activities. Any new council or committee established under subsection (a) of this section or any expansion of an existing council or committee under this subsection may be terminated by the Surgeon General at, before, or after the termination of the new institute or expansion of the existing institute which occasioned such new council or committee or expansion of an existing council or committee. In the case of any such expansion of an existing council

or committee, the Surgeon General may change the title thereof so as to reflect its new functions.

[FUNCTIONS

[SEC. 433. (a) Where an institute has been established under this part, the Surgeon General shall carry out the purposes of section 301 with respect to the conduct and support of research relating to the disease or diseases to which the activities of the institute are directed, through such institute and in cooperation with the national advisory council or committee established or expanded by reason of the establishment of such institute. The provisions of this subsection shall also be applicable to any institute established by any other provision of this Act to the extent that such institute does not already have the authority conferred by this subsection.

[(b) Upon the appointment of a national advisory council or committee for an institute established under this part or the expansion of an existing institute pursuant to this part, such council or committee shall assume the duties, functions, and powers of the National Advisory Health Council with respect to grants-in-aid for research and training projects relating to the disease or diseases to which the activities of the institute are directed.

[NATIONAL INSTITUTE OF ARTHRITIS, DIABETES, AND DIGESTIVE AND KIDNEY DISEASES

[SEC. 434. (a) The Research Institute on Arthritis, Rheumatism, and Metabolic Diseases established under section 431(a) is designated the "National Institute of Arthritis, Diabetes, and Digestive and Kidney Diseases", and the Advisory Council established under section 432 to advise the Secretary with respect to the activities of the Institute is designated the "National Arthritis, Diabetes, and Digestive and Kidney Diseases Advisory Council".

[(b) In the National Institute of Arthritis, Diabetes, and Digestive and Kidney Diseases (hereinafter referred to in this section as the "Institute") there shall be an Associate Director for Arthritis and Musculoskeletal and Skin Diseases, an Associate Director for Diabetes, Endocrinology, and Metabolic Diseases, and Associate Director for Digestive Diseases, and an Associate Director for Kidney, Urologic, and Hematologic Diseases who, under the supervision of the Director of the Institute, shall be responsible for—

[(1) developing a coordinated plan (including recommendations for expenditures) for each of the national research institutes within the National Institutes of Health with respect to research and training concerning the diseases for which the positions of the Associate Directors were created;

[(2) assessing the adequacy of management approaches for the activities within such institutes concerning such diseases and developing improved approaches if needed;

[(3) monitoring and reviewing expenditures by such institutes concerning such diseases; and

[(4) identifying research opportunities concerning such diseases and recommending ways to utilize such opportunities.

The Director of the Institute shall transmit to the Director of the National Institutes of Health the plans, recommendations, and re-

views of the Associate Directors under paragraphs (1) through (4) together with such comments and recommendations as the Director of the institute determines appropriate.

[(c) There are established within the Advisory Council of the Institute a subcommittee on diabetes and endocrine and metabolic diseases, a subcommittee on arthritis and musculoskeletal and skin diseases, a subcommittee on digestive diseases, and a subcommittee on kidney, urologic, and hematologic diseases. The subcommittees shall be composed of members of the Advisory Council who are outstanding in the diagnosis, prevention, and treatment of the diseases for which the subcommittees are established and members of the Advisory Council who are leaders in the fields of education and public affairs. The subcommittees are authorized to review applications made to the Director for grants for research and training projects relating to the diagnosis, prevention, and treatment of the diseases for which the subcommittees are established and shall recommend to the Advisory Council those applications and contracts that the subcommittees determine will best carry out the purposes of this part. The subcommittees shall also review and evaluate the diabetes and endocrine and metabolic diseases, arthritis, musculoskeletal and skin diseases, digestive diseases, and kidney, urologic, and hematologic diseases programs under this part and recommend to the Advisory Council such changes in the administration of such programs as the subcommittees determine are necessary.

[(d) The Director of the Institute, acting through the Associate Director for Arthritis and Musculoskeletal and Skin Diseases, the Associate Director for Kidney, Urologic, and Hematologic Diseases, the Associate Director for Digestive Diseases, and the Associate Director for Diabetes, Endocrinology, and Metabolic Diseases, shall—

[(1) carry out programs of support for research and training (other than training for which National Research Service Awards may be made under section 472) in the diagnosis, prevention, and treatment of arthritis, musculoskeletal and skin diseases, digestive diseases, diabetes mellitus, and endocrine and metabolic, kidney, urologic, and hematologic diseases, including support for training in medical schools, graduate clinical training, graduate training in epidemiology, epidemiology studies, clinical trials, and interdisciplinary research programs; and

[(2) establish programs of evaluation, planning, and dissemination of knowledge related to such research and training.

[(e) The Director of the Institute shall, as soon as practicable, but not later than sixty days, after the end of each fiscal year, prepare, in consultation with the National Advisory Council, and submit to the President and to the Congress an annual report. The annual report shall include a description of the Institute's activities—

[(1) under the current arthritis plan prepared under the National Arthritis Act of 1974,

[(2) under the current diabetes plan prepared under the National Diabetes Mellitus Research and Education Act, and

[(3) under the current digestive diseases plan prepared under the Arthritis, Diabetes, and Digestive Diseases Amendments of 1976. 435

[DIABETES RESEARCH AND TRAINING CENTERS; DIABETES DATA GROUP AND CLEARINGHOUSE

[SEC. 435. (a) Consistent with applicable recommendations of the current diabetes plan under the National Diabetes Mellitus Research and Education Act, the Secretary shall provide for the development, or substantial expansion, of centers for research and training in diabetes mellitus and related endocrine and metabolic disorders. Each center developed or expanded under this section shall (1) utilize the facilities of a single institution, or be formed from a consortium of cooperating institutions, meeting such research and training qualifications as may be prescribed by the Secretary; and (2) conduct (A) research in the diagnosis and treatment of diabetes mellitus and related endocrine and metabolic disorders and the complications resulting from such disease or disorders, (B) training programs for physicians and allied health personnel in current methods of diagnosis and treatment of such disease, disorders, and complications, and (C) information programs for physicians and allied health personnel who provide primary care for patients with such disease, disorders, or complications. Insofar as practicable, centers developed or expanded under this section shall be located geographically on the basis of population density throughout the United States and in environments with proven research capabilities. A center may use funds provided under this subsection to provide stipends for health professionals enrolled in training programs described in clause (2)(B).

[(b) The Secretary shall evaluate on an annual basis the activities of centers developed or expanded under this section and shall report to the Congress (on or before November 30 of each year) the results of his evaluation.

[(c)(1) The Secretary, with the Associate Director for Diabetes, Endocrinology, and Metabolic Diseases, shall (A) establish the Diabetes Data Group and the Diabetes Information Clearinghouse, and (B) through such entities, establish the diabetes data system for the collection, storage, analysis, retrieval, and dissemination of data concerning diabetes, including, where possible, data involving general populations for the purpose of detecting individuals with a risk of developing diabetes.

[(2) There is authorized to be appropriated to carry out this subsection $2,000,000 for the fiscal year ending September 30, 1981; $2,000,000 for the fiscal year ending September 30, 1982; and $2,000,000 for the fiscal year ending September 30, 1983.

[(d) There are authorized to be appropriated to carry out this section (other than subsection (c)) $8,000,000 for fiscal year ending June 30, 1975, $12,000,000 for fiscal year ending June 30, 1976, $20,000,000 for fiscal year ending June 30, 1977, $12,000,000 for the fiscal year ending September 30, 1978, $20,000,000 for the fiscal year ending September 30, 1979, $20,000,000 for the fiscal year ending September 30, 1980, $14,000,000 for the fiscal year ending September 30, 1981, $17,000,000 for the fiscal year ending September 30, 1982, and $20,000,000 for the fiscal year ending September 30, 1983.

[INTERAGENCY COORDINATING COMMITTEES

[SEC. 436. (a) For the purpose of—

[(1) better coordinating the research activities of all the national research institutes relating to arthritis, diabetes mellitus, and digestive diseases; and

[(2) coordinating those aspects of all Federal health programs and activities relating to such diseases to assure the adequacy and technical soundness of such programs and activities and to provide for the full communication and exchange of information necessary to maintain adequate coordination of such programs and activities,

the Secretary shall establish an Arthritis Interagency Coordinating Committee, a Diabetes Mellitus Interagency Coordinating Committee, and a Digestive Diseases Interagency Coordinating Committee (hereinafter in this section individually referred to as a "Committee").

[(b) Each Committee shall be composed of the Directors (or their designees) of each of the national research institutes and divisions involved in research regarding the diseases with respect to which the Committee is established, the Associate Director of the National Institute of Arthritis, Diabetes, and Digestive and Kidney Diseases for the diseases for which the Committee is established, and chief medical director (or the director's designee) of the Veterans' Administration, and a medical officer designated by the Department of Defense, and shall include representation from all other Federal departments and agencies whose programs involve health functions or responsibilities relevant to such diseases, as determined by the Secretary. Each Committee shall be chaired by the Director of the National Institutes of Health (or the Director's designee). Each Committee shall meet at the call of the chairman, but not less often than four times a year.

[(c) Each Committee shall prepare an annual report for—

[(1) the Secretary,

[(2) the Director of the National Institutes of Health, and

[(3) the Advisory Board established under section 437 for the disease for which the Committee was established.

detailing the work of the Committee in the fiscal year for which the report was prepared in carrying out the coordinating activities described in paragraphs (1) and (2) of subsection (a). Such report shall be submitted not later than the sixtieth day after the end of each fiscal year.

[DIABETES, ARTHRITIS, AND DIGESTIVE DISEASES ADVISORY BOARDS

[SEC. 437. (a) The Secretary shall establish the National Arthritis Advisory Board, the National Diabetes Advisory Board, and the National Digestive Diseases Advisory Board (hereinafter in this section individually referred to as an "Advisory Board").

[(b) Each Advisory Board shall be composed of eighteen appointed members and nonvoting, ex officio members as follows:

[(1) The Secretary shall appoint—

[(A) twelve members from individuals who are scientists, physicians, and other health professionals, who are not officers or employees of the United States, and who

represent the specialities and disciplines relevant to the diseases with respect to which the Advisory Board is established; and

[(B) six members from the general public who are knowledgeable with respect to such diseases, including at least one member who is a person who suffers from the disease and one member who is a parent of a person who suffers from the disease.

Of the appointed members, at least five shall by virtue of training or experience be knowledgeable in health education, nursing, data systems, public information, or community program development.

[(2) The following shall be ex officio members of each Advisory Board: The Assistant Secretary for Health, the Director of the National Institutes of Health, the Director of the National Institute of Arthritis, Diabetes, and Digestive and Kidney Diseases, the Director of the Center for Disease Control, the chief medical director of the Veterans' Administration, a medical officer designated by the Department of Defense (or the designees of such ex officio members), the Associate Director of the National Institute of Arthritis, Diabetes, and Digestive and Kidney Diseases for the diseases for which the Board is established, and such other officers and employees of the United States as the Secretary deems necessary for the Advisory Board to carry out its functions. In the case of the National Diabetes Advisory Board, the following shall also be ex officio members: The Director of the National Heart, Lung, and Blood Institute, the Director of the National Eye Institute, the Director of the National Institute of Child Health and Human Development, the Administrator of the Health Resources Administration, and the Administrator of the Health Services Administration (or their designees of such ex officio members).

[(c) Members of an Advisory Board who are officers or employees of the Federal Government shall serve as members of the Advisory Board without compensation in addition to that received in their regular public employment. Other members of the Board shall receive compensation at rates not to exceed the daily equivalent of the annual rate in effect for grade GS-18 of the General Schedule for each day (including traveltime) they are engaged in the performance of their duties as members of the Board.

[(d) The term of office of an appointed member of an Advisory Board is three years, except that no term of office may extend beyond the expiration of the Advisory Board. Any member appointed to fill a vacancy for an unexpired term shall be appointed for the remainder of such term. A member may serve after the expiration of the member's term until a successor has taken office. If a vacancy occurs in an Advisory Board, the Secretary shall make an appointment to fill the vacancy not later than ninety days from the date the vacancy occurs. In the case of the National Diabetes Advisory Board and the National Arthritis Advisory Board, six of the members of each such Advisory Board whose terms expired on September 30, 1980, shall be reappointed for a term of three years.

[(e) The members of each Advisory Board shall select a chairman from among the appointed members.

[(f) The Secretary shall, after consultation with and consideration of the recommendations of an Advisory Board, provide the Advisory Board with an executive director and one other professional staff member. In addition, the Secretary shall, after consultation with and consideration of the recommendations of the Advisory Board, provide the Advisory Board with such additional professional staff members, such clerical staff members, and (through contracts or other arrangements) with such administrative support services and facilities, such information, and such services of consultants, as the Secretary determines are necessary for the Advisory Board to carry out its functions.

[(g) Each Advisory Board shall meet at the call of the chairman or upon request of the Director of the National Institute for Arthritis, Diabetes, and Digestive and Kidney Diseases, but not less often than four times a year.

[(h) Each Advisory Board shall—

[(1) review and evaluate the implementation of the plan referred to in section 434(e) regarding the diseases with respect to which the Advisory Board was established;

[(2) periodically update the plan referred to in paragraph (1) to ensure its continuing relevance;

[(3) for the purpose of assuring the most effective use and organization of resources respecting such diseases, advise and make recommendations to Congress, the Secretary, the Director of the National Institutes of Health, the Director of the National Institute for Arthritis, Diabetes, and Digestive and Kidney Diseases, and the heads of other appropriate Federal agencies for the implementation of such plan; and

[(4) maintain liaison with other advisory bodies related to Federal agencies involved in the implementation of such plan, the Coordinating Committee for such diseases, and with key non-Federal entities involved in activities affecting the control of such diseases.

[(i) In carrying out its functions, the Advisory Board may establish subcommittees, convene workshops and conferences, and collect data. Such subcommittees may be composed of Advisory Board members and nonmember consultants with expertise in the particular area addressed by such subcommittees. The subcommittees may hold such meetings as are necessary to enable them to carry out their activities.

[(j) Each Advisory Board shall submit to the Secretary and Congress an annual report which—

[(1) describes the Advisory Board's activities in the fiscal year for which the report is made;

[(2) describes and evaluates the progress made during such year in research, treatment, education, and training with respect to the diseases with respect to which the Advisory Board was established;

[(3) summarizes and analyzes expenditures made by the Federal Government for activities respecting such diseases in the fiscal year for which the report is made; and

[(4) contains the Advisory Board's recommendations, if any, for changes in the plan referred to in subsection (h)(1).

[(k) For each Advisory Board there is authorized to be appropriated $300,000 for the fiscal year ending September 30, 1981; $300,000 for the fiscal year ending September 30, 1982; and $300,000 for the fiscal year ending September 30, 1983.

[(l) Each Advisory Board shall expire on September 30, 1983.

[ARTHRITIS DEMONSTRATION PROJECTS AND DATA SYSTEM

[SEC. 438. (a) The Secretary may make grants to public and nonprofit entities to establish and support projects for the development and demonstration of methods for arthritis, screening, detection, and referral and for dissemination of these methods to the health and allied health professions. Activities under such projects shall be coordinated with (1) Federal, State, local, and regional health agencies, (2) centers assisted under section 439, and (3) the data system established under subsection (c).

[(b) Projects under this section shall include programs which—

[(1) emphasize the development and demonstration of new and improved methods of screening and early detection, referral, and diagnosis of individuals with a risk of developing arthritis, asymptomatic arthritis, or symptomatic arthritis;

[(2) emphasize the development and demonstration of new and improved methods for patient referral from local hospitals and physicians to appropriate centers for early diagnosis and treatment;

[(3) emphasize the development and demonstration of new and improved means of standardizing patient data and record-keeping;

[(4) emphasize the development and demonstration of new and improved methods of dissemination of knowledge about the projects and methods referred to in the preceding paragraphs of this subsection to health and allied health professionals;

[(5) emphasize the development and demonstration of new and improved methods for the dissemination to the general public of information—

[(A) on the importance of early detection of arthritis, of seeking prompt treatment, and of following an appropriate regimen; and

[(B) to discourage the promotion and use of unapproved and ineffective diagnostic, preventive, treatment, and control methods for arthritis and unapproved and ineffective drugs and devices for arthritis; and

[(6) projects for the investigation into the epidemiology of all forms and aspects of arthritis, including investigations into the social, environmental, behavioral, nutritional, and genetic determinants and influences involved in the epidemiology of arthritis.

[(c)(1) As soon as practical after the date of enactment of this section the Secretary, through the Assistant Secretary for Health, shall establish the Arthritis Data System for the collection, storage, analysis, retrieval, and dissemination of data derived from patient populations with asymptomatic and symptomatic types of arthritis, including where possible, data involving general populations for

the purpose of detection of individuals with a risk of developing arthritis.

[(2) The Secretary shall provide for standardization of patient data and recordkeeping for the collection, storage, analysis, retrieval, and dissemination of such data in cooperation with projects under this section and centers assisted under section 439, and other persons engaged in arthritis programs.

[(d)(1) There are authorized to be appropriated to carry out this section $2,000,000 for fiscal year ending June 30, 1975, $3,000,000 for fiscal year ending June 30, 1976, and $4,000,000 for fiscal year ending June 30, 1977.

[(2) There are authorized to be appropriated to carry out subsections (a) and (b) $3,000,000 for the fiscal year ending September 30, 1978, $4,000,000 for the fiscal year ending September 30, 1979, and $5,000,000 for the fiscal year ending September 30, 1980, and for each of the next 3 fiscal years.

[(3) There are authorized to be appropriated to carry out subsection (c) $1,000,000 for the fiscal year ending September 30, 1978, $1,250,000 for the fiscal year ending September 30, 1979, and $1,500,000 for the fiscal year ending September 30, 1980, and for each of the next 3 fiscal years.

[MULTIPURPOSE ARTHRITIS CENTERS

[SEC. 439. (a) The Secretary may, after consultation with the National Advisory Council established under section 434(a) and consistent with the Arthritis Plan developed pursuant to the National Arthritis Act of 1974, provide for the development, modernization, and operation (including staffing, and other operating costs such as the costs of patient care required for research) of new and existing centers for arthritis research, screening, detection, diagnosis, prevention, control, and treatment, for education related to arthritis, and for the rehabilitation of individuals who suffer from arthritis. For purposes of this section, the term "modernization" means the alteration, remodeling, improvement, expansion, and repair of existing buildings and the provision of equipment for such buildings to the extent necessary to make them suitable for use as centers described in the preceding sentence.

[(b) Each center assisted under this section shall—

[(1)(A) use the facilities of a single institution or a consortium of cooperating institutions, and (B) meet such qualifications as may be prescribed by the Secretary; and

[(2) conduct—

[(A) basic and clinical research into the cause, diagnosis, early detection, prevention, control, and treatment of, arthritis and complications resulting from arthritis, including research into implantable biomaterials and biomechanical and other orthopedic procedures and in the development of other diagnostic and treatment methods;

[(B) training programs for physicians and other health and allied professionals in current methods of diagnosis, screening and early detection, prevention, control, and treatment of arthritis, and in research in arthritis;

[(C) information and continuing education programs for physicians and other health and allied health professionals who provide care for patients with arthritis; and

[(D) programs for the dissemination to the general public of information—

[(i) on the importance of early detection of arthritis, of seeking prompt treatment, and of following an appropriate regimen; and

[(ii) to discourage the promotion and use of unapproved and ineffective diagnostic, preventive, treatment, and control methods and unapproved and ineffective drugs and devices.

A center may use funds provided under this subsection to provide stipends for health professionals enrolled in training programs described in paragraph (2)(B).

[(c) Each center assisted under this section may conduct programs to—

[(1) develop new and improved methods of screening and early detection, referral, and diagnosis or individuals with a risk of developing arthritis, asymptomatic arthritis, or symptomatic arthritis,

[(2) disseminate the results of research, screening, and other activities, and develop means of standardizing patient data and recordkeeping, and

[(3) develop community consultative services to facilitate the referral of patients to centers for treatment.

[(d) The Secretary shall, insofar as practicable, provide for an equitable geographical distribution of centers assisted under this section. The Secretary shall give appropriate consideration to the need for centers especially suited to meeting the needs of children affected by arthritis.

[(e) The Secretary shall evaluate on an annual basis the activities of centers receiving support under this section and shall report to the appropriate committees of Congress the results of his evaluations on or before November 30 of each year.

[(f) For purposes of this section, there are authorized to be appropriated $11,000,000 for the fiscal year ending June 30, 1975, $8,000,000 for the fiscal year ending June 30, 1976, $20,000,000 for the fiscal year ending June 30, 1977, $18,700,000 for the fiscal year ending September 30, 1978, $19,000,000 for the fiscal year ending September 30, 1979, $20,000,000 for the fiscal year ending September 30, 1980, $14,000,000 for the fiscal year ending September 30, 1981, $17,000,000 for the fiscal year ending September 30, 1982, and $20,000,000 for the fiscal year ending September 30, 1983.

[INFORMATION AND EDUCATION CENTER FOR DIGESTIVE DISEASES

[SEC. 440. The Secretary, acting through the Director of the National Institute of Arthritis, Diabetes, and Digestive and Kidney Diseases, shall establish an information and education center for digestive diseases (1) to identify, collect, analyze, and disseminate information respecting the diseases, and (2) to serve as a national educational resource for patients with such diseases and their families, physicians, and other health professionals.

[COORDINATING COMMITTEE FOR DIGESTIVE DISEASES

[SEC. 440A. (a) The Secretary shall establish a Coordinating Committee for Digestive Diseases (hereafter in this section referred to as the "Committee") to be composed of the Directors (or their designated representatives) of each of the Institutes of the National Institutes of Health involved in digestive disease research; and the head (or his designated representative) of the Alcohol, Drug Abuse and Mental Health Administration, the National Institute of Occupational Safety and Health, the Food and Drug Administration, the Department of Medicine and Surgery of the Veterans' Administration, the Center for Disease Control, the Department of Defense, the Department of Agriculture, the Health Services Administration, the Health Resources Administration, the Social Security Administration, and the Institute of Medicine of the National Academy of Sciences. The Committee shall be chaired by the Director of the National Institute of Arthritis, Metabolism, and Digestive Diseases and the Associate Director for Digestive Diseases and Nutrition of that Institute shall serve as vice chairman. The Committee shall meet at the call of the Chairman, but not less often than three times a year.

[(b) The Committee shall be responsible for the coordination of the activities of the entities represented on the Committee respecting digestive diseases. The Committee shall submit to the Secretary an annual report detailing the manner in which the Committee has coordinated such activities.

[PART E—INSTITUTES OF CHILD HEALTH AND HUMAN DEVELOPMENT AND OF GENERAL MEDICAL SCIENCES

[ESTABLISHMENT OF INSTITUTE OF CHILD HEALTH AND HUMAN DEVELOPMENT

[SEC. 441. (a) The Surgeon General is authorized, with the approval of the Secretary, to establish in the Public Health Service the National Institute of Child Health and Human Development for the conduct and support of research and training relating to maternal health, child health, and human development, including research and training in the special health problems and requirements of mothers and children and in the basic sciences relating to the process of human growth and development, including prenatal development.

[(b) The Secretary shall carry out through the National Institute of Child Health and Human Development the purposes of section 301 with respect to the conduct and support of research which specifically relates to sudden infant death syndrome.

[ESTABLISHMENT OF INSTITUTE OF GENERAL MEDICAL SCIENCES

[SEC. 442. The Surgeon General is authorized, with the approval of the Secretary, to establish in the Public Health Service an institute for the conduct and support of research and training in the general or basic medical sciences and related natural or behavioral sciences which have significance for two or more other institutes,

or are outside the general area of responsibility of any other institute, established under or by this Act.

[ESTABLISHMENT OF ADVISORY COUNCILS

[SEC. 443. (a) The Surgeon General is authorized, with the approval of the Secretary, to establish an advisory council or committee to advise, consult with, and make recommendations to the Surgeon General on matters relating to the activities of the institute established under section 441. He may also, with such approval, establish such a council or committee with respect to the activities of the institute established under section 442.

[(b) The provisions relating to the composition, terms of office of members, and reappointment of members of advisory councils or committees under section 432(a) shall be applicable to any council or committee established under this section, except that, in lieu of the requirement in such section that six of the members be outstanding in the study, diagnosis, or treatment of a disease or diseases, six of such members shall be selected from leading medical or scientific authorities who are outstanding in the field of research or training with respect to which the council or committee is being established, and except that the Surgeon General, with the approval of the Secretary, may include on any such council or committee established under this section such additional ex officio members as he deems necessary in the light of the functions of the institute with respect to which it is established.

[(c) Upon appointment of any such council or committee, it shall assume all or such part as the Surgeon General may, with the approval of the Secretary, specify of the duties, functions, and powers of the National Advisory Health Council relating to the research or training projects with which such council or committee established under this part is concerned and such portion as the Surgeon General may specify (with such approval) of the duties, functions, and powers of any other advisory council or committee established under this Act relating to such projects.

[FUNCTIONS

[SEC. 444. The Secretary shall, through an institute established under this part, carry out the purposes of section 301 with respect to the conduct and support of research which is a function of such institute, except that the Secretary shall, in accordance with section 441(b) determine the areas in which and the extent to which he will carry out such purposes of section 301 through such institute or an institute established by or under other provisions of this Act, or both of them, when both institutes have functions with respect to the same subject matter.

[PRESERVATION OF EXISTING AUTHORITY

[SEC. 445. Nothing in this part shall be construed as affecting the authority of the Secretary under section 2 of the Act of April 9, 1912 (42 U.S.C. 192), or title V of the Social Security Act (42 U.S.C., ch. 7, subch. V), or as affecting the authority of the Surgeon General to utilize institutes established under other provisions of this Act

for research or training activities relating to maternal health, child health, and human development or to the general medical sciences and related sciences.

[PART F—NATIONAL EYE INSTITUTE

ESTABLISHMENT OF NATIONAL EYE INSTITUTE

[SEC. 451. The Secretary is authorized to establish in the Public Health Service an institute for the conduct and support of research for new treatment and cures and training relating to blinding eye diseases and visual disorders, including research and training in the special health problems and requirements of the blind and in the basic and clinical sciences relating to the mechanism of the visual function and preservation of sight. The Secretary is also authorized to plan for research and training, especially against the main causes of blindness and loss of visual function.

[ESTABLISHMENT OF ADVISORY COUNCIL

[SEC. 452. (a) The Secretary is authorized to establish an advisory council or committee to advise, consult with, and make recommendations to him on matters relating to the activities of the National Eye Institute.

[(b) The provisions relating to the composition, terms of office of members, and reappointment of members of advisory councils under section 432(a) shall be applicable to the council or committee established under this section, except that the Secretary may include on such council or committee established under this section such additional ex officio members as he deems necessary.

[(c) Upon appointment of such council or committee, it shall assume all or such part as the Secretary may specify of the duties, functions, and powers of the National Advisory Health Council relating to the research or training projects with which such council or committee established under this part is concerned and such portion as the Secretary may specify of the duties, functions, and powers of any other advisory council or committee established under this Act relating to such projects.

[FUNCTIONS

[SEC. 453. The Secretary shall, through the National Eye Institute established under this part, carry out the purposes of section 301 with respect to the conduct and support of research with respect to blinding eye diseases and visual disorders associated with general health and well-being, including the special health problems and requirements of the blind and the mechanism of sight and visual function, except that the Secretary shall determine the areas in which and the extent to which he will carry out such purposes of section 301 through such Institute or an institute established by or under other provisions of this Act, or both of them, when both such institutes have functions with respect to the same subject matter. The Secretary, through the Institute, may, effective October 1, 1978, and without regard to section 405, carry out a program of grants for public and nonprofit private vision research facilities.

[PART G—NATIONAL INSTITUTE OF MENTAL HEALTH

[ESTABLISHMENT OF INSTITUTE

[SEC. 455.[1]

[PART H—NATIONAL INSTITUTE ON AGING

[ESTABLISHMENT OF NATIONAL INSTITUTE ON AGING

[SEC. 461. The Secretary shall establish in the Service an institute to be known as the National Institute on Aging (hereinafter in this part referred to as the "Institute") for the conduct and support of biomedical, social, and behavioral research and training related to the aging process and the diseases and other special problems and needs of the aged.

[NATIONAL ADVISORY COUNCIL ON AGING

[SEC. 462. (a) The Secretary shall establish a National Advisory Council on Aging to advise, consult with, and make recommendations to him on programs relating to the aged which are administered by him and on those matters which relate to the Institute.

[(b) The provisions relating to the composition, terms of office of members, and reappointment of members of advisory councils under section 432(a) shall be applicable to the Advisory Council established under this section, except that (1) the Secretary may include on such Advisory Council such additional ex officio members as he deems necessary, and (2) the Secretary shall appoint to the Council leading medical or scientific authorities skilled in aspects of the biological and the behaviorial sciences relating to aging.

[(c) Upon appointment of such Advisory Council, it shall assume all, or such part as the Secretary may specify, of the duties, functions, and powers of the National Advisory Health Council relating to programs for the aged with which the Advisory Council established under this part is concerned and such portion as the Secretary may specify of the duties, functions, and powers of any other advisory council established under this Act relating to programs for the aged.

[FUNCTIONS

[SEC. 463. (a) The Secretary (1) shall, through the Institute, carry out the purposes of section 301 with respect to research investigations, experiments, demonstrations, and studies related to the aging process and the diseases and other special problems and needs of the aged, except that the Secretary shall determine the area in which and the extent to which he will carry out such activities in furtherance of the purposes of section 301 through the Institute or another institute established by or under other provisions of this Act, or both of them, when both such institutes have functions with respect to the same subject matter and (2) shall be responsible for coordinating such activities so as to avoid unproductive and unnecessary overlap and duplication of such functions.

[1] Section 455 was redesignated as section 504 and transferred to title V.

The Secretary may also provide training and instruction and establish traineeships and fellowships, in the Institute and elsewhere, in matters relating to study and investigation of the aging process and the diseases and other special problems and needs of the aged. The Secretary may provide trainees and fellows participating in such training and instruction or in such traineeships and fellowships with such stipends and allowances (including travel and subsistence expenses and dependency allowances) as he deems necessary, and, in addition, provide for such training, instruction, traineeships, fellowships through grants to public or other nonprofit institutions. In carrying out his health manpower training responsibilities under this Act or any other Act, the Secretary shall take appropriate steps to insure the education and training of adequate numbers of allied health, nursing, and paramedical personnel in the field of health care for the aged.

[(b) The Secretary shall, through the Institute, conduct scientific studies to measure the impact on the biological, medical, and psychological aspects of aging of all programs and activities assisted or conducted by the Department of Health, Education, and Welfare.

[(c) The Secretary, through the Institute, shall carry out public information and education programs designed to disseminate as widely as possible the findings of Institute-sponsored and other relevant aging research and studies and other information about the process of aging which may assist elderly and near-elderly persons in dealing with, and all Americans in understanding, the problems and processes associated with growing older.

[RESEARCH PROGRAM

[SEC. 464. (a) The Secretary, in consultation with the Institute and the National Advisory Council on Aging and such other appropriate advisory bodies as he may establish, shall within two years after the effective date of this section develop a plan for a research program on aging designed to coordinate and promote research into the biological, medical, psychological, social, educational, and economic aspects of aging. Such program shall be carried out, as to research involving the functions of the Institute, primarily through the Institute, and as to other research shall be carried out through any other institute established by or under other provisions of this Act or through any appropriate agency or other organizational unit within the Department of Health, Education, and Welfare.

[(b) Upon its completion, the plan for a research program on aging, required by subsection (a) of this section, shall be transmitted to the Congress and to the President and shall set forth the staffing and funding requirements to carry out such program.

[PART I—GENERAL PROVISIONS

[DIRECTORS OF INSTITUTES

[SEC. 471. The Director of the National Institutes of Health shall be appointed by the President by and with the advice and consent of the Senate; and the Director of the National Cancer Institute shall be appointed by the President. Except as provided in section

404(a)(8), the Director of the National Cancer Institute shall report directly to the Director of the National Institutes of Health.

[NATIONAL RESEARCH SERVICE AWARDS

[SEC. 472. (a)(1) The Secretary shall—

[(A) provide National Research Service Awards for—

[(i) biomedical and behavioral research at the National Institutes of Health and the Alcohol, Drug Abuse, and Mental Health Administration or under programs administered by the Division of Nursing of the Health Resources Administration, in matters relating to the cause, diagnosis, prevention, and treatment of the diseases or other health problems to which the activities of the Institutes and Administration or Division of Nursing are directed,

[(ii) training at the Institutes and Administration of individuals to undertake such research,

[(iii) biomedical and behavioral research at public institutions and at nonprofit private institutions, and

[(iv) pre- and post-doctoral training at such public and private institutions of individuals to undertake biomedical and behavioral research; and

[(B) make grants to public institutions and to nonprofit private institutions to enable such institutions to make to individuals selected by them National Research Service Awards for research (and training to undertake biomedical and behavioral research and the research described in subparagraph (A)(vi)) in the matters described in subparagraph (A)(i).

A reference in this subsection to the National Institutes of Health or the Alcohol, Drug Abuse, and Mental Health Administration shall be considered to include the institutes, divisions, and bureaus included in the Institutes or under the Administration, as the case may be.

[(2) National Research Service Awards may not be used to support residencies.

[(3) In awarding National Research Service Awards under this section, the Secretary shall take account of the Nation's overall need for biomedical research personnel by giving special consideration to physicians who agree to undertake a minimum of two years of biomedical research.

[(b)(1) No national Research Service Award may be made by the Secretary to any individual unless—

[(A) the individual has submitted to the Secretary an application therefor and the Secretary has approved the application;

[(B) the individual provides, in such form and manner as the Secretary shall by regulation prescribe, assurances satisfactory to the Secretary that the individual will meet the service requirement of subsection (c)(1); and

[(C) in the case of a National Research Service Award for a purpose described in subsection (a)(1)(A)(iii), the individual has been sponsored (in such manner as the Secretary may by regulation require) by the institution at which the research or training under the Award will be conducted.

An application for an Award shall be in such form, submitted in such manner, and contain such information, as the Secretary may by regulation prescribe.

[(2) The making of grants under subsection (a)(1)(B) for National Research Service Awards shall be subject to review and approval by the appropriate advisory councils within the Department of Health and Human Services (A) whose activities relate to the research or training under the Awards, or (B) at which such research or training will be conducted.

[(3) No grant may be made under subsection (a)(1)(B) unless an application therefor has been submitted to and approved by the Secretary. Such application shall be in such form, submitted in such manner, and contain such information, as the Secretary may by regulation prescribe. Subject to the provisions of this section other than paragraph (1) of this subsection, National Research Service Awards made under a grant under subsection (a)(1)(B) shall be made in accordance with such regulations as the Secretary shall prescribe.

[(4) The period of any National Research Service Award made to any individual under subsection (a) may not exceed—

[(A) five years in the aggregate for predoctoral training, and

[(B) three years in the aggregate for postdoctoral training,

unless the Secretary for good cause shown waives the application of such limit to such individual.

[(5) National Research Service Awards shall provide for such stipends, tuition, fees, and allowances (including travel and subsistence expenses and dependency allowances), adjusted periodically to reflect increases in the cost of living for the recipients of the Awards as the Secretary may deem necessary. A National Research Service Award made to an individual for research of research training at a non-Federal public or nonprofit private institution shall also provide for payments to be made to the institution for the cost of support services (including the cost of faculty salaries, supplies, equipment, general research support, and related items) provided such individual by such institution. The amount of any such payments to any institution shall be determined by the Secretary and shall bear a direct relationship to the reasonable costs of the institution for establishing and maintaining the quality of its biomedical and behavioral research and training programs.

[(c)(1) Each individual who is awarded a National Research Service Award (other than an individual who is a prebaccalaureate student who is awarded a National Research Service Award for research training) shall, in accordance with paragraph (3), engage in health research or teaching or any combination thereof which is in accordance with the usual patterns of academic employment, for a period computed in accordance with paragraph (2).

[(2) For each month for which an individual receives a National Research Service Award which is made for a period in excess of twelve months, such individual shall engage in one month of health research or teaching or any combination thereof which is in accordance with the usual patterns of academic employment.

[(3) The requirement of paragraph (1) shall be complied with by any individual to whom it applies within such reasonable period of time, after the completion of such individual's Award, as the Secre-

tary shall by regulation prescribe. The Secretary shall by regulation prescribe the type of research and teaching in which an individual may engage to comply with such requirement and such other requirements respecting research and teaching as the Secretary considers appropriate.

[(4)(A) If any individual to whom the requirement of paragraph (1) is applicable fails, within the period prescribed by paragraph (3), to comply with such requirements, the United States shall be entitled to recover from such individual an amount determined in accordance with the formula—

$$A = \phi(t - s/t)$$

in which "A" is the amount the United States is entitled to recover; "ϕ" is the sum of the total amount paid under one or more National Research Service Awards to such individual; "t" is the total number of months in such individual's service obligation; and "s" is the number of months of such obligation served by him in accordance with paragraphs (1) and (2) of this subsection.

[(B) Any amount which the United States is entitled to recover under subparagraph (A) shall, within the three-year period beginning on the date the United States becomes entitled to recover such amount, be paid to the United States. Until any amount due the United States under subparagraph (A) on account of any National Research Service Award is paid, there shall accrue to the United States interest on such amount at a rate fixed by the Secretary of the treasury after taking into consideration private consumer rates of interest prevailing on the date the United States becomes entitled to such amount.

[(5)(A) Any obligation of any individual under paragraph (3) shall be canceled upon the death of such individual.

[(B) The Secretary shall by regulation provide for the waiver or suspension of any such obligation applicable to any individual whenever compliance by such individual is impossible or would involve substantial hardship to such individual and if enforcement of such obligation with respect to any individual would be against equity and good conscience.

[(d) There are authorized to be appropriated to make payments under National Research Service Awards and under grants for such Awards $207,947,000 for this fiscal year ending June 30, 1975, $165,000,000 for fiscal year 1976, $185,000,000 for the fiscal year ending September 30, 1977, $161,390,000 for the fiscal year ending September 30, 1978, $197,500,000 for the fiscal year ending September 30, 1979, $210,000,000 for the fiscal year ending September 30, 1980, $222,500,000 for the fiscal year ending September 30, 1981, $182,000,000 for the fiscal year ending September 30, 1982, and $195,000,000 for the fiscal year ending September 30, 1983. Of the sums appropriated under this subsection, not less than 15 per centum shall be made available for payments under National Research Service awards provided by the Secretary under subsection (a)(1)(A) and not less than 50 per centum shall be made available for grants under subsection (a)(1)(B) for National Research Service Awards. In any fiscal year not more than 4 per centum of the amount obligated to be expended under this section may be obligat-

ed for National Research Service Awards for periods of three months or less.

[STUDIES RESPECTING BIOMEDICAL AND BEHAVIORAL RESEARCH PERSONNEL

[SEC. 473. (a) The Secretary shall, in accordance with subsection (b), arrange for the conduct of a continuing study to—

[(1) establish (A) the nation's overall need for biomedical and behavioral research personnel, (B) the subject areas in which such personnel are needed and the number of such personnel needed in each such area, and (C) the kinds and extent of training which should be provided such personnel;

[(2) assess (A) current training programs available for training of biomedical and behavioral research personnel which are conducted under this Act, at or through institutes under the National Institutes of Health and the Alcohol, Drug Abuse, and Mental Health Administration, and (B) other current training programs available for the training of such personnel;

[(3) identify the kinds of research positions available to and held by individuals completing such programs;

[(4) determine, to the extent feasible, whether the programs referred to in clause (B) of paragraph (2) would be adequate to meet the needs established under paragraph (1) if the programs referred to in clause (A) of paragraph (2) were terminated; and

[(5) determine what modifications in the programs referred to in paragraph (2) are required to meet the needs established under paragraph (1).

[(b)(1) The Secretary shall request the National Academy of Sciences to conduct the study required by subsection (a) under an arrangement under which the actual expenses incurred by such Academy in conducting such study will be paid by the Secretary. If the National Academy of Sciences is willing to do so, the Secretary shall enter into such an arrangement with such Academy for the conduct of such study.

[(2) If the National Academy of Sciences is unwilling to conduct such study under such an arrangement, then the Secretary shall enter into a similar arrangement with other appropriate nonprofit private groups or associations under which such groups or associations will conduct such study and prepare and submit reports thereon as provided in subsection (c).

[(3) The National Academy of Sciences or other group or association conducting the study required by subsection (a) shall conduct such study in consultation with the Director of the National Institutes of Health.

[(c) A report on the results of such study shall be submitted by the Secretary to the Committee on Energy and Commerce of the House of Representatives and the Committee on Labor and Human Resources of the Senate at least once every two years.

[INSTITUTIONAL REVIEW BOARDS; ETHICS GUIDANCE PROGRAM

[SEC. 474. (a) The Secretary shall by regulation require that each entity which applies for a grant or contract under this Act for

any project or program which involves the conduct of biomedical or behavioral research involving human subjects submit in or with its application for such grant or contract assurances satisfactory to the Secretary that it has established (in accordance with regulations which the Secretary shall prescribe) a board (to be known as an "Institutional Review Board") to review biomedical and behavioral research involving human subjects conducted at or sponsored by such entity in order to protect the rights of the human subjects of such research.

[(b) The Secretary shall establish a program within the Department under which requests for clarification and guidance with respect to ethical issues raised in connection with biomedical or behavioral research involving human subjects are responded to promptly and appropriately.

[PEER REVIEW OF GRANT APPLICATIONS AND CONTRACT PROJECTS

[SEC. 475. (a) The Secretary, after consultation with the Director of the National Institutes of Health, and where appropriate, the head of the Division of Nursing of the Health Resources Administration (or the successor to either such entity), shall by regulation require appropriate scientific peer review of—

[(1) applications made after the effective date of such regulations for grants under this Act for biomedical and behavioral research (including research under programs of such Division of Nursing); and

[(2) biomedical and behavioral research and development contract projects to be administered after such effective date through an institute established under this title or the Division of Nursing of the Health Resources Administration (or the successor to either such entity).

[(b) Regulations promulgated under subsection (as) shall, to the extent practical, require that the review of grant applications required by the regulations be conducted—

[(1) in a manner consistent with the system for scientific peer review applicable on the date of the enactment of this section to applications for grants under this Act for biomedical and behavioral research, and

[(2) by peer review groups performing such review on or before such date.

[(c) the members of any peer review group established under such regulations shall be individuals who by virtue of their training or experience are eminently qualified to perform the review functions of the group and not more than one-fourth of the members of any peer review group established under such regulations shall be officers or employees of the United States.

[VISITING SCIENTIST AWARDS

[SEC. 476. (a) The Secretary may make awards (referred to as "Visiting Scientist Awards") to outstanding scientists who agree to serve as visiting scientists at institutions of post-secondary education which have significant enrollments of disadvantaged students. Visiting Scientist Awards shall be made by the Secretary to enable the faculty and students of such institutions to draw upon the spe-

cial talents of scientists from other institutions for the purpose of receiving guidance, advice, and instruction with regard to research, teaching, and curriculum development in the biomedical and behavioral sciences and such other aspects of these sciences as the Secretary shall deem appropriate.

[(b) The amount of each Visiting Scientist Award shall include such sum as shall be commensurate with the salary or remuneration which the individual receiving the award would have been entitled to receive from the institution with which the individual has, or had, a permanent or immediately prior affiliation. Eligibility for and terms of Visiting Scientist Awards shall be determined in accordance with regulations the Secretary shall prescribe.

[APPROPRIATIONS

[SEC. 477. Appropriations to carry out the purposes of this title shall be available for the acquisition of land or the erection of buildings only if so specified, but in the absence of express limitation therein may be expended in the District of Columbia for personal services, stenographic recording the translating services, by contract if deemed necessary, without regard to section 3709 of the Revised Statutes; traveling expenses (including the expenses of attendance at meetings when specifically authorized by the Secretary); rental, supplies and equipment, purchase and exchange of medical books, books of reference, directories, periodicals, newspapers, and press clippings; purchase, operation, and maintenance of motor-propelled passenger-carrying vehicles; printing and binding (in addition to that otherwise provided by law); and for all other necessary expenses in carrying out the provisions of this title.

[OTHER AUTHORITY

[SEC. 478. This title shall not be construed as limiting (1) the functions or authority of the Secretary under any other title of this Act, or of any officer of agency of the United States, relating to the study of the prevention, diagnosis, and treatment of any disease or diseases for which a separate institute is established under this Act; or (2) the expenditure of money therefor.

[EXPERTS AND CONSULTANTS

[SEC. 479. (a) The Director of the National Institutes of Health may obtain (in accordance with section 3109 of title 5, United States Code, but without regard to the limitation in such section on the number of days or the period of service) the services or not more than two hundred experts or consultants who have scientific or professional qualifications, for the National Institutes of Health and for each of the research institutes (other than the National Cancer Institute and the National Heart, Lung, and Blood Institute).

[(b)(1) Experts and consultants whose services are obtained under subsection (a) or under section 404(b)(1) or 413(c)(1) shall be paid or reimbursed for their expenses associated with traveling to and from their assignment location in accordance with sections 5724, 5724a(a)(1), 5724a(a)(3), and 5726(c) of title 5, United States Code.

[(2) Expenses specified in paragraph (1) may not be allowed in connection with the assignment of an expert or consultant whose services are obtained under this subsection, unless and until the expert or consultant agrees in writing to complete the entire period of his assignment or 1 year, whichever is shorter, unless separated or reassigned for reasons beyond his control that are acceptable to the Secretary. If the expert or consultant violates the agreement, the money spent by the United States for these expenses is recoverable from him as a debt to the United States. The Secretary may waive in whole or in part a right of recovery under this subsection with respect to an expert or consultant on assignment with the Secretary.]

PART A—NATIONAL INSTITUTES OF HEALTH

ORGANIZATION OF THE NATIONAL INSTITUTES OF HEALTH

SEC. 401. (a) The National Institutes of Health is an agency of the Service.

(b)(1) The following national research institutes are agencies of the National Institutes of Health:

(A) The National Cancer Institute.

(B) The National Heart, Lung, and Blood Institute.

(C) The National Institute of Diabetes and Digestive and Kidney Diseases.

(D) The National Institute of Arthritis and Musculoskeletal and Skin Diseases.

(E) The National Institute on Aging.

(F) The National Institute of Allergy and Infectious Diseases.

(G) The National Institute of Child Health and Human Development.

(H) The National Institute of Dental Research.

(I) The National Eye Institute.

(J) The National Institute of Neurological and Communicative Disorders and Stroke.

(K) The National Institute of General Medical Sciences.

(L) The National Institute of Environmental Health Sciences.

(2) The following entities are agencies of the National Institutes of Health:

(A) The National Library of Medicine.

(B) The Division of Research Resources.

(C) The John E. Fogarty International Center for Advanced Study in the Health Sciences.

(c)(1) The Secretary may establish in the National Institutes of Health one or more additional national research institutes to conduct and support research, training, health information, and other programs with respect to any particular disease or groups of diseases or any other aspect of human health if—

(A) the Secretary determines that an additional institute is necessary to carry out such activities; and

(B) the additional institute is not established before the expiration of 90 days after the Secretary has provided the Committee on Energy and Commerce of the House of Representatives and the Committee on Labor and Human Resources of the

Senate written notice of the determination made under clause (i) with respect to the institute.

(2) The Secretary may reorganize the functions of any national research institute and may abolish any national research institute if the Secretary determines that the institute is no longer required. A reorganization or abolition may not take effect under this subparagraph before the expiration of 90 days after the Secretary has provided the Committee on Energy and Commerce of the House of Representatives and the Committee on Labor and Human Resources of the Senate written notice of the reorganization or abolition.

(d) For purposes of this title, the term "national research institute" means a national research institute listed in subsection (b) or established under subsection (c). A reference to the National Institutes of Health includes its agencies.

APPOINTMENT AND AUTHORITY OF DIRECTOR OF NIH

SEC. 402. (a) The National Institutes of Health shall be headed by the Director of the National Institutes of Health (hereafter in this title referred to as the "Director of NIH") who shall be appointed by the President by and with the advice and consent of the Senate. The Director of NIH shall perform functions as provided under subsection (b) and as the Secretary may otherwise prescribe.

(b) In carrying out the purposes of section 301, the Secretary, acting through the Director of NIH—

(1) shall be responsible for the overall direction of the National Institutes of Health and for the establishment and implementation of general policies respecting the management and operation of programs and activities within the National Institutes of Health;

(2) shall coordinate and oversee the operation of the national research institutes and administrative entities within the National Institutes of Health;

(3) shall assure that research at the National Institutes of Health is subject to review in accordance with sections 405(c)(3) and 490(b);

(4) for the national research institutes and administrative entities within the National Institutes of Health—

(A) may acquire, construct, improve, repair, operate, and maintain, at the site of such institutes and entities, laboratories, and other research facilities, other facilities, equipment, and other real or personal property, and

(B) may acquire, without regard to the Act of March 3, 1877 (40 U.S.C. 34), by lease or otherwise through the Administrator of General Services, buildings or parts of buildings in the District of Columbia or communities located adjacent to the District of Columbia for use for a period not to exceed ten years;

(5) may secure resources for research conducted by or through the National Institutes of Health;

(6) may, without regard to the provisions of title 5, United States Code, governing appointments in the competitive service, and without regard to the provisions of chapter 51 and subchapter III of chapter 53 of such title relating to classification

and General Schedule pay rates, establish such technical and scientific peer review groups as are needed to carry out the requirements of this title and appoint and pay the members of such groups, except that officers and employees of the United States shall not receive additional compensation for service as members of such groups;

(7) may secure for the National Institutes of Health consultation services and advice of persons from the United States or abroad;

(8) may use, with their consent, the services, equipment, personnel, information, and facilities of other Federal, State, or local public agencies, with or without reimbursement therefor;

(9) may, for purposes of study, admit and treat at facilities of the National Institutes of Health individuals not otherwise eligible for such treatment;

(10) may accept voluntary and uncompensated services; and

(11) may perform such other administrative functions as the Secretary determines are needed to effectively carry out this title.

The Federal Advisory Committee Act shall not apply to any peer review group appointed under paragraph (6). The members of such a group shall be individuals who by virtue of their training or experience are eminently qualified to perform the review functions of such group. Not more than one-fourth of the members of any such group shall be officers or employees of the United States.

(c) The Director of NIH may make available to individuals and entities, for biomedical and behavioral research, substances and living organisms. Such substances and organisms shall be made available under such terms and conditions (including payment for them) as the Secretary determines appropriate.

(d)(1) The Director of NIH may obtain (in accordance with section 3109 of title 5, United States Code, but without regard to the limitation in such section on the period of service) the services of not more than two hundred experts or consultants, with scientific or other professional qualifications, for the National Institutes of Health.

(2)(A) Except as provided in subparagraph (B), experts and consultants whose services are obtained under paragraph (1) shall be paid or reimbursed, in accordance with title 5, United States Code, for their travel and other expenses associated with their assignment.

(B) Expenses specified in subparagraph (A) shall not be allowed in connection with the assignment of an expert or consultant whose services are obtained under paragraph (1) unless the expert or consultant has agreed in writing to complete the entire period of the assignment or one year of the assignment, whichever is shorter, unless separated or reassigned for reasons which are beyond the control of the expert or consultant and which are acceptable to the Secretary. If the expert or consultant violates the agreement, the money spent by the United States for such expenses is recoverable from the expert or consultant as a debt due the United States. The Secretary may waive in whole or in part a right of recovery under this subparagraph.

(e) The Director of NIH shall—

(1) advise the agencies of the National Institutes of Health on medical applications of research;

(2) coordinate, review, and facilitate the systematic identification and evaluation of, clinically relevant information from research conducted by or through the national research institutes;

(3) promote the effective transfer of the information described in paragraph (2) to the health care community and to entities that require such information; and

(4) monitor the effectiveness of the activities described in paragraph (3).

(f) There shall be in the National Institutes of Health an Associate Director for Prevention. The Director of NIH shall delegate to the Associate Director for Prevention the functions of the Director relating to the promotion of the disease prevention research programs of the national research institutes and the coordination of such programs among the national research institutes and between the national research institutes and other public and private entities. The Associate Director shall annually report to the Director of NIH on the prevention activities undertaken by the Associate Director. The report shall include a detailed statement of the expenditures made for the activities reported on and the personnel used in connection with such activities.

REPORT OF DIRECTOR OF NIH

SEC. 403. The Secretary shall transmit to the President and to the Congress a biennial report which shall be prepared by the Director of NIH and which shall consist of—

(1) a description of the activities carried out by and through the National Institutes of Health and the policies respecting the programs of the National Institutes of Health and such recommendations respecting such policies as the Secretary considers appropriate;

(2) a description of the activities undertaken to improve grants and contracting accountability and peer review procedures of the National Institutes of Health and the national research institutes;

(3) the reports made by the Associate Director for Prevention under section 402(f) during the period for which the biennial report is prepared; and

(4) the biennial reports of the Directors of each of the national research institutes.

The first report under this section shall be submitted not later than April 1, 1986, and shall relate to the fiscal year ending on the preceding September 30. The next report shall be submitted not later than December 30, 1988, and shall relate to the two-fiscal-year period ending on the preceding September 30. Each subsequent report shall be submitted not later than 90 days after the end of the two-fiscal-year period for which the report is to be submitted.

PART B—GENERAL PROVISIONS RESPECTING NATIONAL RESEARCH INSTITUTES

APPOINTMENT AND AUTHORITY OF THE DIRECTORS OF THE NATIONAL RESEARCH INSTITUTES

SEC. 405. (a) The Director of the National Cancer Institute shall be appointed by the President and the Directors of the other national research institutes shall be appointed by the Secretary. Each Director of a national research institute shall report directly to the Director of NIH.

(b)(1) In carrying out the purposes of section 301 with respect to the human diseases or disorders or other aspects of human health for which the national research institutes were established, the Secretary, acting through the Director of each national research institute—

(A) shall encourage and support research, investigations, experiments, demonstrations, and studies in the health sciences related to—

(i) the maintenance of health,

(ii) the detection, diagnosis, treatment, and prevention of human diseases and disorders,

(iii) the rehabilitation of individuals with human diseases, disorders, and disabilities, and

(iv) the expansion of knowledge of the processes underlying human diseases, disorders, and disabilities, the processes underlying the normal and pathological functioning of the body and its organ systems, and the processes underlying the interactions between the human organism and the environment;

(B) may, subject to the peer review prescribed under section 490(b) and any advisory council review under section 406(a)(3)(A)(i), conduct the research, investigations, experiments, demonstrations, and studies referred to in subparagraph (A);

(C) may conduct and support research training (i) for which fellowship support is not provided under section 485, and (ii) which is not residency training of physicians or other health professionals;

(D) may develop, implement, and support demonstrations and programs for the application of the results of the activities of the institute to clinical practice and disease prevention activities;

(E) may develop, conduct, and support public and professional education and information programs;

(F) may secure, develop and maintain, distribute, and support the development and maintenance of resources needed for research;

(G) may make available the facilities of the institute to appropriate entities and individuals engaged in research activities and cooperate with and assist Federal and State agencies charged with protecting the public health;

(H) may accept unconditional gifts made to the institute for its activities, and, in the case of gifts of a value in excess of $50,000, establish suitable memorials to the donor;

(I) may secure for the institute consultation services and advice of persons from the United States or abroad;

(J) may use, with their consent, the services, equipment, personnel, information, and facilities of other Federal, State, or local public agencies, with or without reimbursement therefor;

(K) may accept voluntary and uncompensated services; and

(L) may perform such other functions as the Secretary determines are needed to carry out effectively the purposes of the institute.

The indemnification provisions of section 2354, title 10, United States Code, shall apply with respect to contracts entered into under this subsection and section 402(b).

(2) Support for an activity or program under this subsection may be provided through grants, contracts, and cooperative agreements. The Secretary, acting through the Director of each national research institute—

(A) may enter into a contract for research, training, or demonstrations only if the contract has been recommended after peer review required by regulations under section 490; and

(B) may make grants and cooperative agreements under paragraph (1) for research, training, or demonstrations, except that—

(i) if the direct cost of the grant or cooperative agreement to be made does not exceed $50,000, such grant or cooperative agreement may be made only if such grant or cooperative agreement is recommended after peer review required by regulations under section 490, and

(ii) if the direct cost of the grant or cooperative agreement to be made equals or exceeds $50,000, such grant or cooperative agreement may be made only if such grant or cooperative agreement is recommended after peer review required by regulations under section 490 and is recommended under section 406(a)(3)(A)(ii) by the advisory council for the national research institute involved.

(c) In carrying out subsection (b), each Director of a national research institute—

(1) shall coordinate, as appropriate, the activities of the institute with similar programs of other public and private entities;

(2) shall cooperate with the Directors of the other national research institutes in the development and support of multidisciplinary research and research that involves more than one institute; and

(3) may, with the approval of the advisory council for the institute and the Director of NIH, appoint peer review groups in addition to those appointed under section 402(b)(6).

ADVISORY COUNCILS

SEC. 406. (a)(1) Except as provided in subsection (h), the Secretary shall appoint an advisory council for each national research institute which (A) shall advise, assist, consult with, and make recommendations to the Secretary and the Director of such institute on matters related to the activities carried out by and through the in-

stitute and the policies respecting such activities, and (B) shall carry out the special functions prescribed by part C.

(2) Each advisory council for a national research institute may recommend to the Secretary acceptance, in accordance with section 2101, of conditional gifts for study, investigation, or research respecting the diseases, disorders, or other aspect of human health with respect to which the institute was established, for the acquisition of grounds, or for the construction, equipping, or maintenance of facilities for the institute.

(3) Each advisory council for a national research institute—

(A)(i) may on the basis of the materials provided under section 490(b)(2) respecting research conducted at the institute, make recommendations to the Director of the institute respecting such research,

(ii) may review applications for grants and cooperative agreements for research or training and for which advisory council approval is required under section 405(b)(2) and recommend for approval applications for projects which show promise of making valuable contributions to human knowledge, and

(iii) may review any grant, contract, or cooperative agreement proposed to be made or entered into by the institute;

(B) may collect, by correspondence or by personal investigation, information as to studies which are being carried on in the United States or any other country as to the disease, disorders, or other aspect of human health with respect to which the institute was established and with the approval of the Director of the institute make available such information through appropriate publications for the benefit of public and private health entities and health professions personnel and scientists and for the information of the general public; and

(C) may appoint subcommittees and convene workshops and conferences.

(b)(1) Each advisory council shall consist of ex officio members and not more than eighteen members appointed by the Secretary.

(2) The ex officio members of an advisory council shall consist of—

(A) the Secretary, the Director of NIH, the Director of the national research institute for which the council is established, the Chief Medical Director or the Chief Dental Director of the Veterans' Administration, and the Assistant Secretary of Defense for Health Affairs (or the designees of such officers); and

(B) such additional officers or employees of the United States as the Secretary determines necessary for the advisory council to effectively carry out its functions.

(3) The members of an advisory council who are not ex officio members shall be appointed as follows:

(A) Two thirds of the members shall be appointed by the Secretary from among the leading representatives of the health and scientific disciplines relevant to the activities of the national research institute for which the advisory council is established.

(B) One third of the members shall be appointed by the Secretary from the general public and from among leaders in fields of public health, behavioral science, social science, public policy,

law, health policy, economics, and management, and at least one of such members shall be from the general public.

(4) Members of an advisory council who are officers or employees of the United States shall not receive any compensation for service on the advisory council. The other members of an advisory council shall receive, for each day (including traveltime) they are engaged in the performance of the functions of the advisory council, compensation at rates not to exceed the daily equivalent of the annual rate in effect for grade GS–18 of the General Schedule.

(c) The term of office of an appointed member of an advisory council is four years, except that any member appointed to fill a vacancy for an unexpired term shall be appointed for the remainder of such term and the Secretary shall make appointments to an advisory council in such a manner as to ensure that the terms of the members do not all expire in the same year. A member may serve after the expiration of the member's term until a successor has taken office. A member who has been appointed for a term of four years may not be reappointed to an advisory council before two years from the date of expiration of such term of office. If a vacancy occurs in the advisory council among the appointed members, the Secretary shall make an appointment to fill the vacancy within 90 days from the date the vacancy occurs.

(d) The chairman of an advisory council shall be the Director of the national research institute for which the advisory council is established.

(e) The advisory council shall meet at the call of the chairman or upon the request of the Director of the national research institute for which it was established, but at least three times each fiscal year. The location of the meetings of each advisory council is subject to the approval of the Director of the national research institute for which the advisory council was established.

(f) The Director of the national research institute for which an advisory council is established shall designate a member of the staff of the institute to serve as the executive secretary of the advisory council. The Director of such institute shall make available to the advisory council such staff, information, and other assistance as it may require to carry out its functions. The Director of such institute shall provide orientation and training for new members of the advisory council to provide them with such information and training as may be appropriate for their effective participation in the functions of the advisory council.

(g) Each advisory council may prepare, for inclusion in the biennial report made under section 407, (1) comments respecting the activities of the advisory council in the fiscal years respecting which the report is prepared, (2) comments on the progress of the national research institute for which it was established in meeting its objectives, and (3) recommendations respecting the future directions and program and policy emphasis of the institute. Each advisory council may prepare such additional reports as it may determine appropriate.

(h)(1) Except as provided in paragraph (2), this section does not terminate the membership of any advisory council for a national research institute which was in existence on the effective date of the Health Research Extension Act of 1985. After such date—

(A) the Secretary shall make appointments to each such advisory council in such a manner as to bring about as soon as practicable the composition for such council prescribed by this section;

(B) each advisory council shall organize itself in accordance with this section and exercise the functions prescribed by this section; and

(C) the Director of each national research institute shall perform for such advisory council the functions prescribed by this section.

(2)(A) The National Cancer Advisory Board shall be the advisory council for the National Cancer Institute. This section applies to the National Cancer Advisory Board, except that—

(i) appointments to such Board shall be made by the President;

(ii) the term of office of an appointed member shall be 6 years;

(iii) of the members appointed to the Board, not less than five members shall be individuals knowledgeable in environmental carcinogenesis (including carcinogenesis involving occupational and dietary factors);

(iv) the chairman of the Board shall be selected by the President from the appointed members and shall serve as chairman for a term of two years;

(v) the ex officio members of the Board shall be the Secretary, the Director of the Office of Science and Technology Policy, the Director of NIH, the Chief Medical Director of the Veterans' Administration, the Director of the National Institute for Occupational Safety and Health, the Director of the National Institute of Environmental Health Sciences, the Secretary of Labor, the Commissioner of the Food and Drug Administration, the Administrator of the Environmental Protection Agency, the Chairman of the Consumer Product Safety Commission, and the Assistant Secretary of Defense for Health Affairs (or the designees of such officers); and

(vi) the Board shall meet at least four times each fiscal year.

(B) This section applies to the advisory council to the National Heart, Lung, and Blood Institute, except that such advisory council shall meet at least four times each fiscal year.

BIENNIAL REPORT

SEC. 407. The Director of each national research institute, after consultation with the advisory council for the institute, shall prepare for inclusion in the biennial report made under section 403 a biennial report which shall consist of a description of the activities of the institute and program policies of the Director of the institute in the fiscal years respecting which the report is prepared. The Director of each national research institute may prepare such additional reports as the Director determines appropriate. The Director of each national research institute shall provide the advisory council for the institute an opportunity for the submission of the written comments referred to in section 406(g).

AUTHORIZATIONS OF APPROPRIATIONS

SEC. 408. (a) In addition to amounts otherwise authorized to be appropriated under this title for the National Institutes of Health, the following amounts are authorized to be appropriated:

(1)(A) For the National Cancer Institute (other than its programs under section 412), there are authorized to be appropriated $1,194,000,000 for fiscal year 1986, $1,270,000,000 for fiscal year 1987, and $1,344,000,000 for fiscal year 1988.

(B) For the programs under section 412, there are authorized to be appropriated $68,000,000 for fiscal year 1986, $74,000,000 for fiscal year 1987, and $80,000,000 for fiscal year 1988.

(2)(A) For the National Heart, Lung, and Blood Institute (other than its programs under section 419), there are authorized to be appropriated $809,000,000 for fiscal year 1986, $871,000,000 for fiscal year 1987, and $927,000,000 for fiscal year 1988. Of the amount appropriated under this subsection for any such fiscal year, not less than 15 percent of such amount shall be reserved for programs respecting diseases of the lung and not less than 15 percent of such amount shall be reserved for programs respecting blood diseases and blood resources.

(B) For the programs under section 419, there are authorized to be appropriated $82,000,000 for fiscal year 1986, $90,000,000 for fiscal year 1987, and $98,000,000 for fiscal year 1988.

(b)(1) Not later than December 31, 1987, and December 31 of each succeeding year, the Secretary shall report to the Congress the amount obligated in the fiscal year preceding such date for administrative expenses of the National Institutes of Health and the total amount appropriated for the National Institutes of Health for such fiscal year. The Secretary shall consult with the Comptroller General in preparing each report.

(2) For purposes of paragraph (1), the term "administrative expenses" means expenses incurred for the support of activities relevant to the award of grants, contracts, and cooperative agreements, and expenses incurred for general administration of the scientific programs and activities of the National Institutes of Health. In identifying expenses incurred for such support and administration, the Secretary shall consult with the Comptroller General of the United States.

PART C—SPECIFIC PROVISIONS RESPECTING NATIONAL RESEARCH INSTITUTES

SUBPART 1—NATIONAL CANCER INSTITUTE

PURPOSE OF INSTITUTE

SEC. 410. The general purpose of the National Cancer Institute (hereafter in this subpart referred to as the "Institute") is the conduct and support of research, training, health information dissemination, and other programs with respect to the cause, diagnosis, prevention, and treatment of cancer and the continuing care of cancer patients and the families of cancer patients.

NATIONAL CANCER PROGRAM

SEC. 411. The National Cancer Program shall consist of (1) an expanded, intensified, and coordinated cancer research program encompassing the research programs conducted and supported by the Institute and the related research programs of the other national research institutes, including an expanded and intensified research program for the prevention of cancer caused by occupational or environmental exposure to carcinogens, and (2) the other programs and activities of the Institute.

CANCER CONTROL PROGRAMS

SEC. 412. The Director of the Institute shall establish and support demonstration, education, and other programs for the detection, diagnosis, prevention, and treatment of cancer and for rehabilitation and counseling respecting cancer. Programs established and supported under this section shall include—

(1) locally initiated education and demonstration programs (and regional networks of such programs) to transmit research results and to disseminate information respecting—

(A) the detection, diagnosis, prevention, and treatment of cancer,

(B) the continuing care of cancer patients and the families of cancer patients, and

(C) rehabilitation and counseling respecting cancer,

to physicians and other health professionals who provide care to individuals who have cancer;

(2) the demonstration of and the education of students of the health professions and health professionals in—

(A) effective methods for the prevention and early detection of cancer and the identification of individuals with a high risk of developing cancer, and

(B) improved methods of patient referral to appropriate centers for early diagnosis and treatment of cancer; and

(3) the demonstration of new methods for the dissemination of information to the general public concerning the prevention, early detection, diagnosis, and treatment and control of cancer and information concerning unapproved and ineffective methods, drugs, and devices for the diagnosis, prevention, treatment, and control of cancer.

SPECIAL AUTHORITIES OF THE DIRECTOR

SEC. 413. (a) The Director of the Institute shall establish an information and education center to collect, identify, analyze, and disseminate on a timely basis, through publications and other appropriate means, to cancer patients and their families, physicians and other health professionals, and the general public, information on cancer research, diagnosis, prevention, and treatment (including information respecting nutrition programs for cancer patients and the relationship between nutrition and cancer). The Director of the Institute may take such action as may be necessary to insure that all channels for the dissemination and exchange of scientific knowledge and information are maintained between the Institute and other sci-

entific, medical, and biomedical disciplines and organizations nationally and internationally.

(b) The Director of the Institute in carrying out the National Cancer Program—

(1) shall establish or support the large-scale production or distribution of specialized biological materials and other therapeutic substances for cancer research and set standards of safety and care for persons using such materials;

(2) shall, in consultation with the advisory council for the Institute, support (A) research in the cancer field outside the United States by highly qualified foreign nationals which can be expected to benefit the American people, (B) collaborative research involving American and foreign participants, and (C) the training of American scientists abroad and foreign scientists in the United States;

(3) shall, in consultation with the advisory council for the Institute, support appropriate programs of education (including continuing education) and training in fundamental sciences and clinical disciplines in order to enable investigators, physicians, and allied health professionals to participate in clinical programs relating to cancer;

(4) shall encourage and coordinate cancer research by industrial concerns where such concerns evidence a particular capability for such research;

(5) may obtain (with the approval of the advisory council for the Institute and in accordance with section 3109 of title 5, United States Code, but without regard to the limitation in such section on the period of service) the services of not more than one hundred and fifty-one experts or consultants who have scientific or professional qualifications;

(6)(A) may, in consultation with the advisory council for the Institute, acquire, construct, improve, repair, operate, and maintain laboratories, other research facilities, equipment, and such other real or personal property as the Director determines necessary;

(B) may, in consultation with the advisory council for the Institute, make grants for construction or renovation of facilities; and

(C) may, in consultation with the advisory council for the Institute, acquire, without regard to the Act of March 3, 1877 (40 U.S.C. 34), by lease or otherwise through the Administrator of General Services, buildings or parts of buildings in the District of Columbia or communities located adjacent to the District of Columbia for the use of the Institute for a period not to exceed ten years;

(7) may, in consultation with the advisory council for the Institute, appoint one or more advisory committees composed of such private citizens and officials of Federal, State, and local governments to advise the Director with respect to the Director's functions;

(8) may, subject to section 405(b)(2) and without regard to section 3324 of title 31, United States Code, and section 3709 of the Revised Statutes (41 U.S.C. 5), enter into such contracts, leases, cooperative agreements, as may be necessary in the conduct of

functions of the Director, with any public agency, or with any person, firm, association, corporation, or educational institution;

(9) shall maintain and operate the International Cancer Research Data Bank, which shall collect, catalog, store, and disseminate insofar as feasible through the use of information systems accessible to the public, general practitioners, and oncologic investigators, the results of cancer research and treatment undertaken in any country for the use of any person involved in cancer research and treatment in any country; and

(10)(A) shall, notwithstanding section 405(a), prepare and submit, directly to the President for review and transmittal to Congress, an annual budget estimate (including an estimate of the number and type of personnel needs for the Institute) for the National Cancer Program, after reasonable opportunity for comment (but without change) by the Secretary, the Director of NIH, and the Institute's advisory council; and (B) may receive from the President and the Office of Management and Budget directly all funds appropriated by Congress for obligation and expenditure by the Institute.

(c) Except as otherwise provided, experts and consultants whose services are obtained under paragraph (5) of subsection (b) shall be paid or reimbursed, in accordance with title 5, United States Code, for their travel to and from their place of service and for other expenses associated with their assignment. Such expenses shall not be allowed in connection with the assignment of an expert or consultant whose services are obtained under such paragraph unless the expert or consultant has agreed in writing to complete the entire period of the assignment or one year of the assignment, whichever is shorter, unless separated or reassigned for reasons which are beyond the control of the expert or consultant and which are acceptable to the Director of the Institute. If the expert or consultant violates the agreement, the money spent by the United States for such expenses is recoverable from the expert or consultant as a debt due the United States. The Secretary may waiver in whole or in part a right of recovery under this subsection.

NATIONAL CANCER RESEARCH AND DEMONSTRATION CENTERS

SEC. 414. (a) The Director of the Institute is authorized to provide for the establishment of new centers for basic and clinical research into, training in, and demonstration of, advanced diagnostic, prevention, and treatment methods for cancer. Such centers may be supported under subsection (b) or under any other applicable provision of law.

(b)(1) The Director of the Institute, under policies established by the Director of NIH and after consultation with the advisory council to the Institute, is authorized to enter into cooperative agreements with public or private nonprofit agencies or institutions to pay all or part of the cost of planning, establishing, or strengthening, and providing basic operating support for existing or new centers for basic and clinical research into, training in, and demonstration of advanced diagnostic, prevention, and treatment methods for cancer.

(2) Federal payments made under this subsection in support of a cooperative agreement under paragraph (1) may be used for—

(A) construction (notwithstanding any limitation under section 494);

(B) staffing and other basic operating costs, including such patient care costs as are required for research;

(C) clinical training, including training for allied health professionals, continuing education for health professionals and allied health professions personnel, and information programs for the public respecting cancer; and

(D) demonstration purposes.

(c) As used in this section, the term "construction" does not include the acquisition of land, and the term "training" does not include research training for which National Research Service Awards may be provided under section 485.

(d) Support of a center under this section may be for a period of not to exceed five years. Such period may be extended by the Director for additional periods of not more than five years each if the operations of such center have been reviewed by an appropriate scientific review group established by the Director and if such group has recommended to the Director that such period should be extended.

PRESIDENT'S CANCER PANEL

SEC. 415. (a)(1) The President's Cancer Panel (hereafter in this section referred to as the "Panel") shall be composed of three persons appointed by the President who by virtue of their training, experience, and background are exceptionally qualified to appraise the National Cancer Program. At least two members of the Panel shall be distinguished scientists or physicians.

(2)(A) Members of the Panel shall be appointed for three-year terms, except that (i) any member appointed to fill a vacancy occurring prior to the expiration of the term for which the member's predecessor was appointed shall be appointed only for the remainder of such term, and (ii) a member may serve until the member's successor has taken office. If a vacancy occurs in the Panel, the President shall make an appointment to fill the vacancy not later than 90 days after the date the vacancy occurred.

(B) The President shall designate one of the members to serve as the chairman of the Panel for a term of one year.

(C) Members of the Panel shall each be entitled to receive the daily equivalent of the annual rate of basic pay in effect for grade GS–18 of the General Schedule for each day (including traveltime) during which they are engaged in the actual performance of duties as members of the Panel and shall be allowed travel expenses (including a per diem allowance) under section 5703 of title 5, United States Code.

(3) The Panel shall meet at the call of the chairman, but not less often than four times a year. A transcript shall be kept of the proceedings of each meeting of the Panel, and the chairman shall make such transcript available to the public.

(b) The Panel shall monitor the development and execution of the activities of the National Cancer Program, and shall report directly

to the President. Any delays or blockages in rapid execution of the Program shall immediately be brought to the attention of the President. The Panel shall submit to the President periodic progress reports on the Program and shall submit to the President, the Secretary, and the Congress an annual evaluation of the efficacy of the Program and suggestions for improvements, and shall submit such other reports as the President shall direct.

ASSOCIATE DIRECTOR FOR PREVENTION

SEC. 416. (a) There shall be in the Institute an Associate Director for Prevention to coordinate and promote the programs in the Institute concerning the prevention of cancer. The Associate Director shall be appointed by the Director of the Institute from individuals who because of their professional training or experience are experts in public health or preventive medicine.

(b) The Associate Director for Prevention shall prepare for inclusion in the biennial report made under section 407 a description of the prevention activities of the Institute, including a description of the staff and resources allocated to those activities.

SUBPART 2—NATIONAL HEART, LUNG, AND BLOOD INSTITUTE

PURPOSE OF THE INSTITUTE

SEC. 418. The general purpose of the National Heart, Lung, and Blood Institute (hereafter in this subpart referred to as the "Institute") is the conduct and support of research, training, health information dissemination, and other programs with respect to heart, blood vessel, lung, and blood diseases and with respect to the use of blood and blood products and the management of blood resources.

HEART, BLOOD VESSEL, LUNG, AND BLOOD DISEASE PREVENTION AND CONTROL PROGRAMS

SEC. 419. The Director of the Institute, under policies established by the Director of NIH and after consultation with the advisory council for the Institute, shall establish programs as necessary for cooperation with other Federal health agencies, State, local, and regional public health agencies, and nonprofit private health agencies in the diagnosis, prevention, and treatment (including the provision of emergency medical services) of heart, blood vessel, lung, and blood diseases, appropriately emphasizing the prevention, diagnosis, and treatment of such diseases of children.

INFORMATION AND EDUCATION

SEC. 420. The Director of the Institute shall collect, identify, analyze, and disseminate on a timely basis, through publications and other appropriate means, to patients, families of patients, physicians and other health professionals, and the general public, information on research, prevention, diagnosis, and treatment of heart, blood vessel, lung, and blood diseases, the maintenance of health to reduce the incidence of such diseases, and on the use of blood and blood products and the management of blood resources. In carrying out this section the Director of the Institute shall place special emphasis upon—

(1) the dissemination of information regarding diet and nutrition, environmental pollutants, exercise, stress, hypertension, cigarette smoking, weight control, and other factors affecting the prevention of arteriosclerosis and other cardiovascular diseases and of pulmonary and blood diseases; and

(2) the dissemination of information designed to encourage children to adopt healthful habits respecting the risk factors related to the prevention of such diseases.

NATIONAL HEART, BLOOD VESSEL, LUNG, AND BLOOD DISEASES AND BLOOD RESOURCES PROGRAM

SEC. 421. (a)(1) The National Heart, Blood Vessel, Lung, and Blood Diseases and Blood Resources Program (hereafter in this subpart referred to as the "Program") may provide for—

(A) investigation into the epidemiology, etiology, and prevention of all forms and aspects of heart, blood vessel, lung, and blood diseases, including investigations into the social, environmental, behavioral, nutritional, biological, and genetic determinants and influences involved in the epidemiology, etiology, and prevention of such diseases;

(B) studies and research into the basic biological processes and mechanisms involved in the underlying normal and abnormal heart, blood vessel, lung, and blood phenomena;

(C) research into the development, trial, and evaluation of techniques, drugs, and devices (including computers) used in, and approaches to, the diagnosis, treatment (including the provision of emergency medical services), and prevention of heart, blood vessel, lung, and blood diseases and the rehabilitation of patients suffering from such diseases;

(D) establishment of programs that will focus and apply scientific and technological efforts involving the biological, physical, and engineering sciences to all facets of heart, blood vessel, lung, and blood diseases with emphasis on the refinement, development, and evaluation of technological devices that will assist, replace, or monitor vital organs and improve instrumentation for detection, diagnosis, and treatment of such diseases;

(E) establishment of programs for the conduct and direction of field studies, large-scale testing and evaluation, and demonstration of preventive, diagnostic, therapeutic, and rehabilitative approaches to, and emergency medical services for, such diseases;

(F) studies and research into blood diseases and blood, and into the use of blood for clinical purposes and all aspects of the management of blood resources in the United States, including the collection, preservation, fractionation, and distribution of blood and blood products;

(G) the education (including continuing education) and training of scientists, clinical investigators, and educators in fields and specialties (including computer sciences) requisite to the conduct of clinical programs respecting heart, blood vessel, lung, and blood diseases and blood resources;

(H) public and professional education relating to all aspects of such diseases, including the prevention of such diseases, and

the use of blood and blood products and the management of blood resources;

(I) establishment of programs for study and research into heart, blood vessel, lung, and blood diseases of children (including cystic fibrosis, hyaline membrane, hemolytic diseases such as sickle cell anemia and Cooley's anemia, and hemophilic diseases) and for the development and demonstration of diagnostic, treatment, and preventive approaches to such diseases; and

(J) establishment of programs for study, research, development, demonstrations, and evaluation of emergency medical services for people who become critically ill in connection with heart, blood vessel, lung, or blood diseases.

(2) The Program shall be coordinated with other national research institutes to the extent that they have responsibilities respecting such diseases and shall give special emphasis to the continued development in the Institute of programs related to the causes of stroke and to effective coordination of such programs with related stroke programs in the National Institute of Neurological and Communicative Disorders and Stroke. The Director of the Institute, with the advice of the advisory council for the Institute, shall revise annually the plan for the Program and shall carry out the Program in accordance with such plan.

(b) In carrying out the Program, the Director of the Institute, under policies established by the Director of NIH—

(1) may, after approval of the advisory council for the Institute, obtain (in accordance with section 3109 of title 5, United States Code, but without regard to the limitation in such section on the period of service) the services of not more than one hundred experts or consultants who have scientific or professional qualifications;

(2)(A) may, in consultation with the advisory council for the Institute, acquire and construct, improve, repair, operate, alter, renovate, and maintain, heart, blood vessel, lung, and blood disease and blood resource laboratory, research, training, and other facilities, equipment, and such other real or personal property as the Director determines necessary;

(B) may, in consultation with the advisory council for the Institute, make grants for construction or renovation of facilities; and

(C) may, in consultation with the advisory council for the Institute, acquire, without regard to the Act of March 3, 1877 (40 U.S.C. 34), by lease or otherwise, through the Administrator of General Services, buildings or parts of buildings in the District of Columbia or communities located adjacent to the District of Columbia for the use of the Institute for a period not to exceed ten years;

(3) subject to section 405(b)(2) and without regard to section 3324 of title 31, United States Code, and section 3709 of the Revised Statutes (41 U.S.C. 5), may enter into such contracts, leases, cooperative agreements, or other transactions, as may be necessary in the conduct of the Director's functions, with any public agency, or with any person, firm, association, corporation, or educational institutions; and

(4) may make grants to public and nonprofit private entities to assist in meeting the cost of the care of patients in hospitals, clinics, and related facilities who are participating in research projects.

(c) Except as otherwise provided, experts and consultants whose services are obtained under paragraph (1) of subsection (b) shall be paid or reimbursed, in accordance with title 5, United States Code, for their travel to and from their place of service and for other expenses associated with their assignment. Such expenses shall not be allowed in connection with the assignment of an expert or consultant whose services are obtained under such paragraph unless the expert or consultant has agreed in writing to complete the entire period of the assignment or one year of the assignment, whichever is shorter, unless separated or reassigned for reasons which are beyond the control of the expert or consultant and which are acceptable to the Director of the Institute. If the expert or consultant violates the agreement, the money spent by the United States for such expenses is recoverable from the expert or consultant as a debt due the United States. The Secretary may waive in whole or in part a right of recovery under this subsection.

NATIONAL RESEARCH AND DEMONSTRATION CENTERS FOR HEART, BLOOD VESSEL, LUNG, AND BLOOD DISEASES, SICKLE CELL ANEMIA, AND BLOOD RESOURCES

SEC. 422. (a)(1) The Director of the Institute may provide, in accordance with subsection (c), for the development of—

(A) ten centers for basic and clinical research into, training in, and demonstration of, advanced diagnostic, prevention, and treatment methods (including methods of providing emergency medical services) for heart and blood vessel diseases;

(B) ten centers for basic and clinical research into, training in, and demonstration of, advanced diagnostic, prevention, and treatment methods (including methods of providing emergency medical services) for lung diseases (including bronchitis, emphysema, asthma, cystic fibrosis, and other lung diseases of children); and

(C) ten centers for basic and clinical research into, training in, and demonstration of, advanced diagnostic, prevention, and treatment methods (including methods of providing emergency medical services) for blood diseases and research into blood, in the use of blood products and in the management of blood resources.

(2) The centers developed under paragraph (1) shall, in addition to being utilized for research, training, and demonstrations, be utilized for the following prevention programs for cardiovascular, pulmonary, and blood diseases:

(A) Programs to develop improved methods of detecting individuals with a high risk of developing cardiovascular, pulmonary, and blood diseases.

(B) Programs to develop improved methods of intervention against those factors which cause individuals to have a high risk of developing such diseases.

(C) Programs to develop health professions and allied health professions personnel highly skilled in the prevention of such diseases.

(D) Programs to develop improved methods of providing emergency medical services for persons with such diseases.

(E) Programs of continuing education for health and allied health professionals in the diagnosis, prevention, and treatment of such diseases and the maintenance of health to reduce the incidence of such diseases and information programs for the public respecting the prevention and early diagnosis and treatment of such diseases and the maintenance of health.

(3) The research, training, and demonstration activities carried out through any such center may relate to any one or more of the diseases referred to in paragraph (1) of this subsection.

(b) The Director of the Institute shall provide, in accordance with subsection (c), for the development of ten centers for basic and clinical research into the diagnosis, treatment, and control of sickle cell anemia.

(c)(1) The Director of the Institute may enter into cooperative agreements with and make grants to public or private nonprofit entities to pay all or part of the cost of planning, establishing, or strengthening, and providing basic operating support for centers for basic and clinical research into, training in, and demonstration of the management of blood resources and advanced diagnostic, prevention, and treatment methods for heart, blood vessel, lung, or blood diseases.

(2) A cooperative agreement or grant under paragraph (1) shall be entered into in accordance with policies established by the Director of NIH and after consultation with the Institute's advisory council.

(3) Federal payments made under a cooperative agreement or grant under paragraph (1) may be used for—

(A) construction (notwithstanding any limitation under section 494);

(B) staffing and other basic operating costs, including such patient care costs as are required for research;

(C) training, including training for allied health professionals; and

(D) demonstration purposes.

(4) As used in this subsection, the term "construction" does not include the acquisition of land, and the term "training" does not include research training for which National Research Service Awards may be provided under section 485.

(5) Support of a center under paragraph (1) may be for a period of not to exceed five years. Such period may be extended by the Director for additional periods of not more than five years each if the operations of such center have been reviewed by an appropriate scientific review group established by the Director and if such group has recommended to the Director that such period should be extended.

INTERAGENCY TECHNICAL COMMITTEE

SEC. 423. (a) The Secretary shall establish an Interagency Technical Committee on Heart, Blood Vessel, Lung and Blood Diseases

and Blood Resources which shall be responsible for coordinating those aspects of all Federal health programs and activities relating to heart, blood vessel, lung, and blood diseases and blood resources to assure the adequacy and technical soundness of such programs and activities and to provide for the full communication and exchange of information necessary to maintain adequate coordination of such programs and activities.

(b) The Director of the Institute shall serve as chairman of the Committee and the Committee shall include representation from all Federal departments and agencies whose programs involve health functions or responsibilities relevant to the functions of the Committee, as determined by the Secretary.

ASSOCIATE DIRECTOR FOR PREVENTION

SEC. 424. (a) There shall be in the Institute an Associate Director for Prevention to coordinate and promote the programs in the Institute concerning the prevention of heart, blood vessel, lung, and blood diseases. The Associate Director shall be appointed by the Director of the Institute from individuals who because of their professional training or experience are experts in public health or preventive medicine.

(b) The Associate Director for Prevention shall prepare for inclusion in the biennial report made under section 407 a description of the prevention activities of the Institute, including a description of the staff and resources allocated to those activities.

SUBPART 3—NATIONAL INSTITUTE OF DIABETES AND DIGESTIVE AND KIDNEY DISEASES

PURPOSE OF THE INSTITUTE

SEC. 426. The general purpose of the National Institute of Diabetes and Digestive and Kidney Diseases (hereafter in this subpart referred to as the "Institute") is the conduct and support of research, training, health information dissemination, and other programs with respect to diabetes mellitus and endocrine and metabolic diseases, digestive diseases and nutritional disorders, and kidney, urologic, and hematologic diseases.

DATA SYSTEMS AND INFORMATION CLEARINGHOUSES

SEC. 427. (a) The Director of the Institute shall (1) establish the National Diabetes Data System for the collection, storage, analysis, retrieval, and dissemination of data derived from patient populations with diabetes, including, where possible, data involving general populations for the purpose of detection of individuals with a risk of developing diabetes, and (2) establish the National Diabetes Information Clearinghouse to facilitate and enhance knowledge and understanding of diabetes on the part of health professionals, patients, and the public through the effective dissemination of information.

(b) The Director of the Institute shall (1) establish the National Digestive Diseases Data System for the collection, storage, analysis, retrieval, and dissemination of data derived from patient populations with digestive diseases, including, where possible, data involv-

ing general populations for the purpose of detection of individuals with a risk of developing digestive diseases, and (2) establish the National Digestive Diseases Information Clearinghouse to facilitate and enhance knowledge and understanding of digestive diseases on the part of health professionals, patients, and the public through the effective dissemination of information.

(c) The Director of the Institute shall (1) establish the National Kidney and Urologic Diseases Data System for the collection, storage, analysis, retrieval, and dissemination of data derived from patient populations with kidney and urologic diseases, including, where possible, data involving general populations for the purpose of detection of individuals with a risk of developing kidney and urologic diseases and (2) establish the National Kidney and Urologic Diseases Information Clearinghouse to facilitate and enhance knowledge and understanding of kidney and urologic diseases on the part of health professionals, patients, and the public through the effective dissemination of information.

DIVISION DIRECTORS FOR DIABETES, ENDOCRINOLOGY, AND METABOLIC DISEASES, DIGESTIVE DISEASES AND NUTRITION, AND KIDNEY, UROLOGIC, AND HEMATOLOGIC DISEASES

SEC. 428. (a)(1) In the Institute there shall be a Division Director for Diabetes, Endocrinology, and Metabolic Diseases, a Division Director for Digestive Diseases and Nutrition, and a Division Director for Kidney, Urologic, and Hematologic Diseases. Such Division Directors, under the supervision of the Director of the Institute, shall be responsible for—

(A) developing a coordinated plan (including recommendations for expenditures) for each of the national research institutes within the National Institutes of Health with respect to research and training concerning diabetes, endocrine and metabolic diseases, digestive diseases and nutrition, and kidney, urologic, and hematologic diseases;

(B) assessing the adequacy of management approaches for the activities within such institutes concerning such diseases and nutrition and developing improved approaches if needed;

(C) monitoring and reviewing expenditures by such institutes concerning such diseases and nutrition; and

(D) identifying research opportunities concerning such diseases and nutrition and recommending ways to utilize such opportunities.

(2) The Director of the Institute shall transmit to the Director of NIH the plans, recommendations, and reviews of the Division Directors under subparagraphs (A) through (D) of paragraph (1) and such comments and recommendations as the Director of the Institute determines appropriate.

(b) The Director of the Institute, acting through the Division Director for Diabetes, Endocrinology, and Metabolic Diseases, the Division Director for Digestive Diseases and Nutrition, and the Division Director for Kidney, Urologic, and Hematologic Diseases shall—

(1) carry out programs of support for research and training (other than training for which National Research Service Awards may be made under section 485) in the diagnosis, pre-

vention, and treatment of diabetes mellitus and endocrine and metabolic diseases, digestive diseases and nutritional disorders, and kidney, urologic, and hematologic diseases, including support for training in medical schools, graduate clinical training, graduate training in epidemiology, epidemiology studies, clinical trials, and interdisciplinary research programs; and

(2) establish programs of evaluation, planning, and dissemination of knowledge related to such research and training.

INTERAGENCY COORDINATING COMMITTEES

SEC. 429. (a) For the purpose of—

(1) better coordination of the research activities of all the national research institutes relating to diabetes mellitus, digestive diseases, and kidney, urologic, and hematologic diseases; and

(2) coordinating those aspects of all Federal health programs and activities relating to such diseases to assure the adequacy and technical soundness of such programs and activities and to provide for the full communication and exchange of information necessary to maintain adequate coordination of such programs and activities;

the Secretary shall establish a Diabetes Mellitus Interagency Coordinating Committee, a Digestive Diseases Interagency Coordinating Committee, and a Kidney, Urologic, and Hematologic Diseases Coordinating Committee (hereafter in this section individually referred to as a "Committee").

(b) Each Committee shall be composed of the Directors of each of the national research institutes and divisions involved in research with respect to the diseases for which the committee is established, the Division Director of the Institute for the diseases for which the committee is established, the Chief Medical Director of the Veterans' Administration, and the Assistant Secretary of Defense for Health Affairs (or the designees of such officers), and shall include representation from all other Federal departments and agencies whose programs involve health functions or responsibilities relevant to such diseases, as determined by the Secretary. Each Committee shall be chaired by the Director of NIH (or the designee of such Director). Each Committee shall meet at the call of the chairman, but not less often than four times a year.

(c) Each Committee shall prepare an annual report for—

(1) the Secretary;

(2) the Director of NIH; and

(3) the Advisory Board established under section 430 for the diseases for which the Committee was established,

detailing the work of the Committee in carrying out paragraphs (1) and (2) of subsection (a) in the fiscal year for which the report was prepared. Such report shall be submitted not later than 120 days after the end of each fiscal year.

ADVISORY BOARDS

SEC. 430. (a) The Secretary shall establish in the Institute the National Diabetes Advisory Board, the National Digestive Diseases Advisory Board, and the National Kidney and Urologic Diseases Advi-

sory Board (hereafter in this section individually referred to as an "Advisory Board").

(b) Each Advisory Board shall be composed of eighteen appointed members and nonvoting ex officio members as follows:

(1) The Secretary shall appoint—

(A) twelve members from individuals who are scientists, physicians, and other health professionals, who are not officers or employees of the United States, and who represent the specialties and disciplines relevant to the diseases with respect to which the Advisory Board is established; and

(B) six members from the general public who are knowledgeable with respect to such diseases, including at least one member who is a person who has such a disease and one member who is a parent of a person who has such a disease.

Of the appointed members, at least five shall by virtue of training or experience be knowledgeable in the fields of health education, nursing, data systems, public information, and community program development.

(2)(A) The following shall be ex officio members of each Advisory Board:

(i) The Assistant Secretary for Health, the Director of NIH, the Director of the National Institute of Diabetes and Digestive and Kidney Diseases, the Director of the Centers for Disease Control, the Chief Medical Director of the Veterans' Administration, the Assistant Secretary of Defense for Health Affairs, and the Division Director of the National Institute of Diabetes and Digestive and Kidney Diseases for the diseases for which the Board is established (or the designees of such officers).

(ii) Such other officers and employees of the United States as the Secretary determines necessary for the Advisory Board to carry out its functions.

(B) In the case of the National Diabetes Advisory Board, the following shall also be ex officio members: The Director of the National Heart, Lung, and Blood Institute, the Director of the National Eye Institute, the Director of the National Institute of Child Health and Human Development, and the Administrator of the Health Resources and Services Administration (or the designees of such officers).

(c) Members of an Advisory Board who are officers or employees of the Federal Government shall serve as members of the Advisory Board without compensation in addition to that received in their regular public employment. Other members of the Board shall receive compensation at rates not to exceed the daily equivalent of the annual rate in effect for grade GS–18 of the General Schedule for each day (including traveltime) they are engaged in the performance of their duties as members of the Board.

(d) The term of office of an appointed member of an Advisory Board is four years, except that no term of office may extend beyond the expiration of the Advisory Board. Any member appointed to fill a vacancy for an unexpired term shall be appointed for the remainder of such term. A member may serve after the expiration of the member's term until a successor has taken office. If a vacancy

occurs in an Advisory Board, the Secretary shall make an appointment to fill the vacancy not later than 90 days from the date the vacancy occurred.

(e) The members of each Advisory Board shall select a chairman from among the appointed members.

(f) The Secretary shall, after consultation with and consideration of the recommendations of an Advisory Board, provide the Advisory Board with an executive director and one other professional staff member. In addition, the Secretary shall, after consultation with and consideration of the recommendations of the Advisory Board, provide the Advisory Board with such additional professional staff members, such clerical staff members, and (through contracts or other arrangements) such administrative support services and facilities, such information, and such services of consultants, as the Secretary determines are necessary for the Advisory Board to carry out its functions.

(g) Each Advisory Board shall meet at the call of the chairman or upon request of the Director of the Institute, but not less often than four times a year.

(h) The National Diabetes Advisory Board and the National Digestive Diseases Advisory Board shall—

(1) review and evaluate the implementation of the plan (referred to in section 433) respecting the diseases with respect to which the Advisory Board was established and periodically update the plan to ensure its continuing relevance;

(2) for the purpose of assuring the most effective use and organization of resources respecting such diseases, advise and make recommendations to the Congress, the Secretary, the Director of NIH, the Director of the Institute, and the heads of other appropriate Federal agencies for the implementation and revision of such plan; and

(3) maintain liaison with other advisory bodies related to Federal agencies involved in the implementation of such plan, the coordinating committee for such diseases, and with key non-Federal entities involved in activities affecting the control of such diseases.

(i) In carrying out its functions, each Advisory Board may establish subcommittees, convene workshops and conferences, and collect data. Such subcommittees may be composed of Advisory Board members and nonmember consultants with expertise in the particular area addressed by such subcommittees. The subcommittees may hold such meetings as are necessary to enable them to carry out their activities.

(j) Each Advisory Board shall prepare an annual report for the Secretary which—

(1) describes the Advisory Board's activities in the fiscal year for which the report is made;

(2) describes and evaluates the progress made in such fiscal year in research, treatment, education, and training with respect to the diseases with respect to which the Advisory Board was established;

(3) summarizes and analyzes expenditures made by the Federal Government for activities respecting such diseases in such fiscal year; and

49-929 O - 85 - 7

(4) contains the Advisory Board's recommendations (if any) for changes in the plan referred to in section 433.

(k) Each Advisory Board shall expire on September 30, 1988.

(l) The National Diabetes Advisory Board and the National Digestive Diseases Advisory Board in existence on the effective date of the Health Research Extension Act of 1985 shall terminate upon the appointment of a successor Board under subsection (a). The Secretary shall make appointments to the Advisory Boards established under subsection (a) before the expiration of 90 days after such effective date. The members of the Boards in existence on such date may be appointed, in accordance with subsections (b) and (d), to the Boards established under subsection (a) for diabetes and digestive diseases, except that at least one-half of the members of the National Diabetes Advisory Board in existence on the effective date of the Health Research Extension Act of 1985 shall be appointed to the National Diabetes Advisory Board first established under subsection (a).

RESEARCH AND TRAINING CENTERS

SEC. 431. (a)(1) Consistent with applicable recommendations of the National Commission on Diabetes, the Director of the Institute shall provide for the development or substantial expansion of centers for research and training in diabetes mellitus and related endocrine and metabolic diseases. Each center developed or expanded under this subsection shall—

(A) utilize the facilities of a single institution, or be formed from a consortium of cooperating institutions, meeting such research and training qualifications as may be prescribed by the Secretary; and

(B) conduct—

(i) research in the diagnosis and treatment of diabetes mellitus and related endocrine and metabolic diseases and the complications resulting from such diseases;

(ii) training programs for physicians and allied health personnel in current methods of diagnosis and treatment of such diseases and complications, and in research in diabetes; and

(iii) information programs for physicians and allied health personnel who provide primary care for patients with such diseases or complications.

(2) A center may use funds provided under this subsection to provide stipends for nurses and allied health professionals enrolled in research training programs described in paragraph (1)(B)(ii).

(b) Consistent with applicable recommendations of the National Digestive Diseases Advisory Board, the Director shall provide for the development or substantial expansion of centers for research in digestive diseases and related functional, congenital, metabolic disorders, and normal development of the digestive tract. Each center developed or expanded under this subsection—

(1) shall utilize the facilities of a single institution, or be formed from a consortium of cooperating institutions, meeting such research qualifications as may be prescribed by the Secretary;

(2) shall develop and conduct basic and clinical research into the cause, diagnosis, early detection, prevention, control, and treatment of digestive diseases and nutritional disorders and related functional, congenital, or metabolic complications resulting from such diseases or disorders;

(3) shall encourage research into and programs for—

(A) providing information for patients with such diseases, disorders, and complications and the families of such patients, physicians and others who care for such patients, and the general public;

(B) model programs for cost effective and preventive patient care; and

(C) training physicians and scientists in research on such diseases, disorders, and complications; and

(4) may perform research and participate in epidemiological studies and data collection relevant to digestive diseases and disorders in order to disseminate such research, studies, and data to the health care profession and to the public.

(c) The Director shall provide for the development, establishment, or substantial expansion of centers for research in kidney and urologic diseases. Each center developed, established, or expanded under this subsection—

(1) shall utilize the facilities of a single institution, or be formed from a consortium of cooperating institutions, meeting such research qualifications as may be prescribed by the Secretary;

(2) shall develop and conduct basic and clinical research into the cause, diagnosis, early detection, prevention, control, and treatment of kidney and urologic diseases;

(3) shall encourage research into and programs for—

(A) providing information for patients with such diseases and the families of such patients, physicians and others who care for such patients, and the general public;

(B) model programs for cost effective and preventive patient care; and

(C) training physicians and scientists in research on such diseases; and

(4) may perform research and participate in epidemiological studies and data collection relevant to kidney and urologic diseases in order to disseminate such research, studies, and data to the health care profession and to the public.

(d) Insofar as practicable, centers developed, established, or expanded under this section should be geographically dispersed throughout the United States and in environments with proven research capabilities. Support of a center under this section may be for a period of not to exceed five years and such period may be extended by the Director of the Institute for additional periods of not more than five years each if the operations of such center have been reviewed by an appropriate scientific review group established by the Director and if such group has recommended to the Director that such period should be extended.

ADVISORY COUNCIL SUBCOMMITTEES

SEC. 432. There are established within the advisory council for the Institute appointed under section 406 a subcommittee on diabetes and endocrine and metabolic diseases, a subcommittee on digestive diseases and nutrition, and a subcommittee on kidney, urologic, and hematologic diseases. The subcommittees shall be composed of members of the advisory council who are outstanding in the diagnosis, prevention, and treatment of the diseases for which the subcommittees are established and members of the advisory council who are leaders in the fields of education and public affairs. The subcommittees are authorized to review applications made to the Director of the Institute for grants for research and training projects relating to the diagnosis, prevention, and treatment of the diseases for which the subcommittees are established and shall recommend to the advisory council those applications and contracts that the subcommittees determine will best carry out the purposes of the Institute. The subcommittees shall also review and evaluate the diabetes and endocrine and metabolic diseases, digestive diseases and nutrition, and kidney, urologic, and hematologic diseases programs of the Institute and recommend to the advisory council such changes in the administration of such programs as the subcommittees determine are necessary.

BIENNIAL REPORT

SEC. 433. The Director of the Institute shall prepare for inclusion in the biennial report made under section 407 a description of the Institute's activities—

(1) under the current diabetes plan under the National Diabetes Mellitus Research and Education Act; and

(2) under the current digestive diseases plan formulated under the Arthritis, Diabetes, and Digestive Diseases Amendments of 1976.

The description submitted by the Director shall include an evaluation of the activities of the centers supported under section 431.

SUBPART 4—NATIONAL INSTITUTE OF ARTHRITIS AND MUSCULOSKELETAL AND SKIN DISEASES

PURPOSE OF THE INSTITUTE

SEC. 435. The general purpose of the National Institute of Arthritis and Musculoskeletal and Skin Diseases (hereafter in this subpart referred to as the "Institute") is the conduct and support of research and training, the dissemination of health information, and other programs with respect to arthritis and musculoskeletal and skin diseases, including sports-related disorders.

NATIONAL ARTHRITIS AND MUSCULOSKELETAL DISEASES PROGRAM

SEC. 436. (a) The Director of the Institute, with the advice of the Institute's advisory council, shall prepare and transmit to the Director of NIH a plan for a national arthritis and musculoskeletal diseases program to expand, intensify, and coordinate the activities of the Institute respecting arthritis and musculoskeletal diseases. The plan shall include such comments and recommendations as the Di-

rector of the Institutes determines appropriate. The Director of the Institute shall periodically review and revise such plan and shall transmit any revisions of such plan to the Director of NIH.

(b) Activities under the national arthritis and musculoskeletal diseases program shall be coordinated with the other national research institutes to the extent that such institutes have responsibilities respecting arthritis and musculoskeletal diseases, and shall, at least, provide for—

(1) investigation into the epidemiology, etiology, and prevention of all forms of arthritis and musculo- skeletal diseases, including sports-related disorders, primarily through the support of basic research in such areas as immunology, genetics, biochemistry, microbiology, physiology, bioengineering, and any other scientific discipline which can contribute important knowledge to the treatment and understanding of arthritis and musculoskeletal diseases;

(2) research into the development, trial, and evaluation of techniques, drugs, and devices used in the diagnosis, treatment, including medical rehabilitation and prevention of arthritis and musculoskeletal diseases;

(3) research on the refinement, development, and evaluation of technological devices that will replace or be a substitute for damaged bone, muscle, and joints and other supporting structures; and

(4) the establishment of mechanisms to monitor the causes of athletic injuries and identify ways of preventing such injuries on scholastic athletic fields.

(c) The Director of the Institute shall carry out the national arthritis and musculoskeletal diseases program in accordance with the plan prepared under subsection (a) and any revisions of such plan made under such subsection.

RESEARCH AND TRAINING

SEC. 437. The Director of the Institute shall—

(1) carry out programs of support for research and training (other than training for which National Research Service Awards may be made under section 485) in the diagnosis, prevention, and treatment of arthritis and musculoskeletal and skin diseases, including support for training in medical schools, graduate clinical training, graduate training in epidemiology, epidemiology studies, clinical trials, and interdisciplinary research programs; and

(2) establish programs of evaluation, planning, and dissemination of knowledge related to such research and training.

DATA SYSTEM AND INFORMATION CLEARINGHOUSE

SEC. 438. (a) The Director of the Institute shall establish the National Arthritis and Musculoskeletal and Skin Diseases Data System for the collection, storage, analysis, retrieval, and dissemination of data derived from patient populations with arthritis and musculoskeletal and skin diseases, including where possible, data involving general populations for the purpose of detection of indi-

viduals with a risk of developing arthritis and musculoskeletal and skin diseases.

(b) The Director of the Institute shall establish the National Arthritis and Musculoskeletal and Skin Diseases Information Clearinghouse to facilitate and enhance, through the effective dissemination of information, knowledge and understanding of arthritis and musculoskeletal and skin diseases by health professionals, patients, and the public.

INTERAGENCY COORDINATING COMMITTEES

SEC. 439. (a) For the purpose of—

(1) better coordination of the research activities of all the national research institutes relating to arthritis, musculoskeletal diseases, and skin diseases, including sports-related disorders; and

(2) coordinating the aspects of all Federal health programs and activities relating to arthritis, musculoskeletal diseases, and skin diseases in order to assure the adequacy and technical soundness of such programs and activities and in order to provide for the full communication and exchange of information necessary to maintain adequate coordination of such programs and activities,

the Secretary shall establish an Arthritis and Musculoskeletal Diseases Interagency Coordinating Committee and a Skin Diseases Interagency Coordinating Committee (hereafter in this section individually referred to as a "Committee").

(b) Each Committee shall be composed of the Directors of each of the national research institutes and divisions involved in research regarding the diseases with respect to which the Committee is established, the Chief Medical Director of the Veterans' Administration, and the Assistant Secretary of Defense for Health Affairs (or the designees of such officers), and representatives of all other Federal departments and agencies (as determined by the Secretary) whose programs involve health functions or responsibilities relevant to arthritis and musculoskeletal diseases or skin diseases, as the case may be. Each Committee shall be chaired by the Director of NIH (or the designee of the Director). Each Committee shall meet at the call of the Chairman, but not less often than four times a year.

(c) Not later than 120 days after the end of each fiscal year, each Committee shall prepare and transmit to the Secretary, the Director of NIH, the Director of the Institute, and the advisory council for the Institute a report detailing the activities of the Committee in such fiscal year in carrying out paragraphs (1) and (2) of subsection (a).

ARTHRITIS AND MUSCULOSKELETAL DISEASES DEMONSTRATION PROJECTS

SEC. 440. (a) The Director of the Institute may make grants to public and private nonprofit entities to establish and support projects for the development and demonstration of methods for screening, detection, and referral for treatment of arthritis and musculoskeletal diseases and for the dissemination of information on such methods to the health and allied health professions. Activities

under such projects shall be coordinated with Federal, State, local, and regional health agencies, centers assisted under section 441, and the data system established under subsection (c).

(b) Projects supported under this section shall include—

(1) programs which emphasize the development and demonstration of new and improved methods of screening and early detection, referral for treatment, and diagnosis of individuals with a risk of developing arthritis and musculoskeletal diseases;

(2) programs which emphasize the development and demonstration of new and improved methods for patient referral from local hospitals and physicians to appropriate centers for early diagnosis and treatment;

(3) programs which emphasize the development and demonstration of new and improved means of standardizing patient data and recordkeeping;

(4) programs which emphasize the development and demonstration of new and improved methods of dissemination of knowledge about the programs, methods, and means referred to in paragraphs (1), (2), and (3) of this subsection to health and allied health professionals;

(5) programs which emphasize the development and demonstration of new and improved methods for the dissemination to the general public of information—

(A) on the importance of early detection of arthritis and musculoskeletal diseases, of seeking prompt treatment, and of following an appropriate regimen; and

(B) to discourage the promotion and use of unapproved and ineffective diagnostic, preventive treatment, and control methods for arthritis and unapproved and ineffective drugs and devices for arthritis and musculoskeletal diseases; and

(6) projects for investigation into the epidemiology of all forms and aspects of arthritis and musculo- skeletal diseases, including investigations into the social, environmental, behavioral, nutritional, and genetic determinants and influences involved in the epidemiology of arthritis and musculoskeletal diseases.

(c) The Director shall provide for the standardization of patient data and recordkeeping for the collection, storage, analysis, retrieval, and dissemination of such data in cooperation with projects assisted under this section, centers assisted under section 441, and other persons engaged in arthritis and musculoskeletal disease programs.

MULTIPURPOSE ARTHRITIS AND MUSCULOSKELETAL DISEASES CENTERS

SEC. 441. (a) The Director of the Institute shall, after consultation with the advisory council for the Institute, provide for the development, modernization, and operation (including staffing and other operating costs such as the costs of patient care required for research) of new and existing centers for arthritis and musculoskeletal diseases. For purposes of this section, the term "modernization" means the alteration, remodeling, improvement, expansion, and

repair of existing buildings and the provision of equipment for such buildings to the extent necessary to make them suitable for use as centers described in the preceding sentence.

(b) Each center assisted under this section shall—

(1)(A) use the facilities of a single institution or a consortium of cooperating institutions, and (B) meet such qualifications as may be prescribed by the Secretary; and

(2) conduct—

(A) basic and clinical research into the cause, diagnosis, early detection, prevention, control, and treatment of arthritis and musculoskeletal diseases and complications resulting from arthritis and musculoskeletal diseases, including research into implantable biomaterials and biomechanical and other orthopedic procedures;

(B) training programs for physicians, scientists, and other health and allied health professionals;

(C) information and continuing education programs for physicians and other health and allied health professionals who provide care for patients with arthritis and musculoskeletal diseases; and

(D) programs for the dissemination to the general public of information—

(i) on the importance of early detection of arthritis and musculoskeletal diseases, of seeking prompt treatment, and of following an appropriate regimen; and

(ii) to discourage the promotion and use of unapproved and ineffective diagnostic, preventive, treatment, and control methods and unapproved and ineffective drugs and devices.

A center may use funds provided under subsection (a) to provide stipends for health professionals enrolled in training programs described in paragraph (2)(B).

(c) Each center assisted under this section may conduct programs to—

(1) establish the effectiveness of new and improved methods of detection, referral, and diagnosis of individuals with a risk of developing arthritis and musculoskeletal diseases;

(2) disseminate the results of research, screening, and other activities, and develop means of standardizing patient data and recordkeeping; and

(3) develop community consultative services to facilitate the referral of patients to centers for treatment.

(d) The Director of the Institute shall, insofar as practicable, provide for an equitable geographical distribution of centers assisted under this section. The Director shall give appropriate consideration to the need for centers especially suited to meeting the needs of children affected by arthritis and musculoskeletal diseases.

(e) Support of a center under this section may be for a period of not to exceed five years. Such period may be extended by the Director of the Institute for one or more additional periods of not more than five years if the operations of such center have been reviewed by an appropriate scientific review group established by the Director and if such group has recommended to the Director that such period should be extended.

ADVISORY BOARD

SEC. 442. (a) The Secretary shall establish in the Institute the National Arthritis Advisory Board (hereafter in this section referred to as the "Advisory Board").

(b) The Advisory Board shall be composed of eighteen appointed members and nonvoting, ex officio members, as follows:

(1) The Secretary shall appoint—

(A) twelve members from individuals who are scientists, physicians, and other health professionals, who are not officers or employees of the United States, and who represent the specialties and disciplines relevant to arthritis, musculoskeletal diseases, and skin diseases; and

(B) six members from the general public who are knowledgeable with respect to such diseases, including at least one member who is a person who has such a disease and one member who is a parent of a person who has such a disease.

Of the appointed members, at least five shall by virtue of training or experience be knowledgeable in health education, nursing, data systems, public information, or community program development.

(2) The following shall be ex officio members of the Advisory Board: The Assistant Secretary for Health, the Director of NIH, the Director of the National Institute of Arthritis and Musculoskeletal and Skin Diseases, the Director of the Centers for Disease Control, the Chief Medical Director of the Veterans' Administration, and the Assistant Secretary of Defense for Health Affairs (or the designees of such officers), and such other officers and employees of the United States as the Secretary determines necessary for the Advisory Board to carry out its functions.

(c) Members of the Advisory Board who are officers or employees of the Federal Government shall serve as members of the Advisory Board without compensation in addition to that received in their regular public employment. Other members of the Advisory Board shall receive compensation at rates not to exceed the daily equivalent of the annual rate in effect for grade GS–18 of the General Schedule for each day (including traveltime) they are engaged in the performance of their duties as members of the Advisory Board.

(d) The term of office of an appointed member of the Advisory Board is four years. Any member appointed to fill a vacancy for an unexpired term shall be appointed for the remainder of such term. A member may serve after the expiration of the member's term until a successor has taken office. If a vacancy occurs in the Advisory Board, the Secretary shall make an appointment to fill the vacancy not later than 90 days after the date the vacancy occurred.

(e) The members of the Advisory Board shall select a chairman from among the appointed members.

(f) The Secretary shall, after consultation with and consideration of the recommendations of the Advisory Board, provide the Advisory Board with an executive director and one other professional staff member. In addition, the Secretary shall, after consultation with and consideration of the recommendations of the Advisory Board,

provide the Advisory Board with such additional professional staff members, such clerical staff members, and (through contracts or other arrangements) with such administrative support services and facilities, such information, and such services of consultants, as the Secretary determines are necessary for the Advisory Board to carry out its functions.

(g) The Advisory Board shall meet at the call of the chairman or upon request of the Director of the Institute, but not less often than four times a year.

(h) The Advisory Board shall—

(1) review and evaluate the implementation of the plan prepared under section 436(a) and periodically update the plan to ensure its continuing relevance;

(2) for the purpose of assuring the most effective use and organization of resources respecting arthritis, musculoskeletal diseases and skin diseases, advise and make recommendations to the Congress, the Secretary, the Director of NIH, the Director of the Institute, and the heads of other appropriate Federal agencies for the implementation and revision of such plan; and

(3) maintain liaison with other advisory bodies for Federal agencies involved in the implementation of such plan, the interagency coordinating committees for such diseases established under section 439, and with key non-Federal entities involved in activities affecting the control of such diseases.

(i) In carrying out its functions, the Advisory Board may establish subcommittees, convene workshops and conferences, and collect data. Such subcommittees may be composed of Advisory Board members and nonmember consultants with expertise in the particular area addressed by such subcommittees. The subcommittees may hold such meetings as are necessary to enable them to carry out their activities.

(j) The Advisory Board shall prepare an annual report for the Secretary which—

(1) describes the Advisory Board's activities in the fiscal year for which the report is made;

(2) describes and evaluates the progress made in such fiscal year in research, treatment, education, and training with respect to arthritis, musculoskeletal diseases, and skin diseases;

(3) summarizes and analyzes expenditures made by the Federal Government for activities respecting such diseases in such fiscal year for which the report is made; and

(4) contains the Advisory Board's recommendations (if any) for changes in the plan prepared under section 436(a).

(k) The National Arthritis Advisory Board in existence on the effective date of the Health Research Extension Act of 1985 shall terminate upon the appointment of a successor Board under subsection (a). The Secretary shall make appointments to the Advisory Board established under subsection (a) before the expiration of 90 days after such effective date. The member of the Board in existence on such date may be appointed, in accordance with subsections (b) and (d), to the Advisory Board established under subsection (a).

SUBPART 5—NATIONAL INSTITUTE ON AGING

PURPOSE OF THE INSTITUTE

SEC. 443. The general purpose of the National Institute on Aging (hereafter in this subpart referred to as the "Institute") is the conduct and support of biomedical, social, and behavioral research, training, health information dissemination, and other programs with respect to the aging process and the diseases and other special problems and needs of the aged.

SPECIAL FUNCTIONS

SEC. 444. (a) In carrying out the training responsibilities under this Act or any other Act for health and allied health professions personnel, the Secretary shall take appropriate steps to insure the education and training of adequate numbers of allied health, nursing, and paramedical personnel in the field of health care for the aged.

(b) The Director of the Institute shall conduct scientific studies to measure the impact on the biological, medical, social, and psychological aspects of aging of programs and activities assisted or conducted by the Department of Health and Human Services.

(c) The Director of the Institute shall carry out public information and education programs designed to disseminate as widely as possible the findings of research sponsored by the Institute, other relevant aging research and studies, and other information about the process of aging which may assist elderly and near-elderly persons in dealing with, and all Americans in understanding, the problems and processes associated with growing older.

(d) The Director of the Institute shall make grants to public and private nonprofit institutions to conduct research relating to Alzheimer's Disease.

ALZHEIMER'S DISEASE CENTERS

SEC. 445. (a)(1) The Director of the Institute may enter into cooperative agreements with and make grants to public or private nonprofit entities to pay all or part of the cost of planning, establishing, or strengthening, and providing basic operating support for centers for basic and clinical research into, training in, and demonstration of advanced diagnostic, prevention, and treatment methods for Alzheimer's Disease.

(2) A cooperative agreement or grant under paragraph (1) shall be entered into in accordance with policies established by the Director of NIH and after consultation with the Institute's advisory council.

(b)(1) Federal payments made under a cooperative agreement or grant under subsection (a) may be used for—

(A) construction (notwithstanding any limitation under section 494);

(B) staffing and other basic operating costs, including such patient care costs as are required for research;

(C) training, including training for allied health professionals; and

(D) demonstration purposes.

(2) As used in this subsection, the term "construction" does not include the acquisition of land, and the term "training" does not include research training for which National Research Service Awards may be provided under section 485.

(c) Support of a center under subsection (a) may be for a period of not to exceed five years. Such period may be extended by the Director for additional periods of not more than five years each if the operations of such center have been reviewed by an appropriate scientific review group established by the Director and if such group has recommended to the Director that such period should be extended.

Subpart 6—National Institute of Allergy and Infectious Diseases

PURPOSE OF THE INSTITUTE

Sec. 446. The general purpose of the National Institute of Allergy and Infectious Diseases is the conduct and support of research, training, health information dissemination, and other programs with respect to allergic and immunologic diseases and disorders and infectious diseases.

Subpart 7—National Institute of Child Health and Human Development

PURPOSE OF THE INSTITUTE

Sec. 448. The general purpose of the National Institute of Child Health and Human Development (hereafter in this subpart referred to as the "Institute") is the conduct and support of research, training, health information dissemination, and other programs with respect to maternal health, child health, mental retardation, human growth and development, including prenatal development, and special health problems and requirements of mothers and children.

SUDDEN INFANT DEATH SYNDROME

Sec. 449. The Director of the Institute shall conduct and support research which specifically relates to sudden infant death syndrome.

MENTAL RETARDATION RESEARCH

Sec. 450. The Director of the Institute shall conduct and support research and related activities with respect to the causes, prevention, and treatment of mental retardation.

ASSOCIATE DIRECTOR FOR PREVENTION

Sec. 451. (a) There shall be in the Institute an Associate Director for Prevention to coordinate and promote the programs in the Institute concerning the prevention of health problems of mothers and children. The Associate Director shall be appointed by the Director of the Institute from individuals who because of their professional training or experience are experts in public health or preventive medicine.

(b) The Associate Director for Prevention shall prepare for inclusion in the biennial report made under section 407 a description of

the prevention activities of the Institute, including a description of the staff and resources allocated to those activities.

Subpart 8—National Institute of Dental Research

PURPOSE OF THE INSTITUTE

Sec. 453. The general purpose of the National Institute of Dental Research is the conduct and support of research, training, health information dissemination, and other programs with respect to the cause, prevention, and methods of diagnosis and treatment of dental and oral diseases and conditions.

Subpart 9—National Eye Institute

PURPOSE OF THE INSTITUTE

Sec. 455. The general purpose of the National Eye Institute (hereafter in this subpart referred to as the "Institute") is the conduct and support of research, training, health information dissemination, and other programs with respect to blinding eye diseases, visual disorders, mechanisms of visual function, preservation of sight, and the special health problems and requirements of the blind. The Director of the Institute may carry out a program of grants for public and private nonprofit vision research facilities.

Subpart 10—National Institute of Neurological and Communicative Disorders and Stroke

PURPOSE OF THE INSTITUTE

Sec. 457. The general purpose of the National Institute of Neurological and Communicative Disorders and Stroke (hereafter in this subpart referred to as the "Institute") is the conduct and support of research, training, health information dissemination, and other programs with respect to neurological disease and disorder, stroke, and disorders of human communication.

SPINAL CORD REGENERATION RESEARCH

Sec. 458. The Director of the Institute shall conduct and support research into spinal cord regeneration.

BIOENGINEERING RESEARCH

Sec. 459. The Director of the Institute shall make grants or enter into contracts for research on the means to overcome paralysis of the extremities through electrical stimulation and the use of computers.

Subpart 11—National Institute of General Medical Sciences

PURPOSE OF THE INSTITUTE

Sec. 461. The general purpose of the National Institute of General Medical Sciences is the conduct and support of research, training, and, as appropriate, health information dissemination, and other programs with respect to general or basic medical sciences and related natural or behavioral sciences which have significance for two or

more other national research institutes or are outside the general area of responsibility of any other national research institute.

Subpart 12—National Institute of Environmental Health Sciences

PURPOSE OF THE INSTITUTE

Sec. 463. The general purpose of the National Institute of Environmental Health Sciences is the conduct and support of research, training, health information dissemination, and other programs with respect to factors in the environment that affect human health, directly or indirectly.

Part D—National Library of Medicine

Subpart 1—General Provisions

PURPOSE AND ESTABLISHMENT OF THE LIBRARY

Sec. 467. In order to assist the advancement of medical and related sciences, and to aid the dissemination and exchange of scientific and other information important to the progress of medicine and to the public health, there is established the National Library of Medicine (hereafter in this part referred to as the "Library").

FUNCTIONS OF THE LIBRARY

Sec. 468. (a) The Secretary, through the Library and subject to subsection (c), shall—

(1) acquire and preserve books, periodicals, prints, films, recordings, and other library materials pertinent to medicine;

(2) organize the materials specified in paragraph (1) by appropriate cataloging, indexing, and bibliographical listings;

(3) publish and disseminate the catalogs, indexes, and bibliographies referred to in paragraph (2);

(4) make available, through loans, photographic or other copying procedures, or otherwise, such materials in the Library as the Secretary determines appropriate;

(5) provide reference and research assistance; and

(6) engage in such other activities as the Secretary determines appropriate and as the Library's resources permit.

(b) The Secretary may exchange, destroy, or otherwise dispose of any books, periodicals, films, and other library materials not needed for the permanent use of the Library.

(c)(1) The Secretary may, after obtaining the advice and recommendations of the Board of Regents, prescribe rules under which the Library will—

(A) provide copies of its publications or materials,

(B) will make available its facilities for research, or

(C) will make available its bibliographic, reference, or other services,

to public and private entities and individuals.

(2) Rules prescribed under paragraph (1) may provide for making available such publications, materials, facilities, or services—

(A) without charge as a public service,

(B) upon a loan, exchange, or charge basis, or

(C) in appropriate circumstances, under contract arrangements made with a public or other nonprofit entity.

(d) Whenever the Secretary, with the advice of the Board of Regents, determines that—

(1) in any geographic area of the United States there is no regional medical library adequate to serve such area;

(2) under criteria prescribed for the administration of section 478, there is a need for a regional medical library to serve such area; and

(3) because there is no medical library located in such area which, with financial assistance under section 478, can feasibly be developed into a regional medical library adequate to serve such area,

the Secretary may establish, as a branch of the Library, a regional medical library to serve the needs of such area.

(e) Section 2101 shall be applicable to the acceptance and administration of gifts made for the benefit of the Library or for carrying out any of its functions, and the Board of Regents shall make recommendations to the Secretary relating to establishment within the Library of suitable memorials to the donors.

(f) For purposes of this part the terms "medicine" and "medical", except when used in section 469, include preventive and therapeutic medicine, dentistry, pharmacy, hospitalization, nursing, public health, and the fundamental sciences related thereto, and other related fields of study, research, or activity.

BOARD OF REGENTS

SEC. 469. (a)(1) The Board of Regents of the National Library of Medicine consists of the Surgeons General of the Public Health Service, the Army, the Navy, and the Air Force, the Chief Medical Director of the Veterans' Administration, the Assistant Director for Biological, Behavioral, and Social Sciences of the National Science Foundation, and the Librarian of Congress, all of whom shall be ex officio members, and ten members appointed by the Secretary. The ten appointed members shall be selected from among leaders in the various fields of the fundamental sciences, medicine, dentistry, public health, hospital administration, pharmacology, health communications technology, or scientific or medical library work, or in public affairs. At least six of the appointed members shall be selected from among leaders in the fields of medical, dental, or public health research or education.

(2) The Board shall annually elect one of the appointed members to serve as Chairman until the next election. The Secretary shall designate a member of the Library staff to act as executive secretary of the Board.

(b) The Board shall advise, consult with, and make recommendations to the Secretary on matters of policy in regard to the Library, including such matters as the acquisition of materials for the Library, the scope, content, and organization of the Library's services, and the rules under which its materials, publications, facilities, and services shall be made available to various kinds of users. The Secretary shall include in the annual report of the Secretary to the

Congress a statement covering the recommendations made by the Board and the disposition thereof. The Secretary may use the services of any member of the Board in connection with matters related to the work of the Library, for such periods, in addition to conference periods, as the Secretary may determine.

(c) Each appointed member of the Board shall hold office for a term of four years, except that any member appointed to fill a vacancy occurring prior to the expiration of the term for which the predecessor of such member was appointed shall be appointed for the remainder of such term. None of the appointed members shall be eligible for reappointment within one year after the end of the preceding term of such member.

LIBRARY FACILITIES

SEC. 470. There are authorized to be appropriated amounts sufficient for the erection and equipment of suitable and adequate buildings and facilities for use of the Library. The Administrator of General Services may acquire, by purchase, condemnation, donation, or otherwise, a suitable site or sites, selected by the Secretary in accordance with the direction of the Board, for such buildings and facilities and to erect thereon, furnish, and equip such buildings and facilities. The amounts authorized to be appropriated by this section include the cost of preparation of drawings and specifications, supervision of construction, and other administrative expenses incident to the work. The Administrator of General Services shall prepare the plans and specifications, make all necessary contracts, and supervise construction.

SUBPART 2—FINANCIAL ASSISTANCE

AUTHORIZATION OF APPROPRIATIONS

SEC. 472. For the purpose of grants and contracts under sections 475, 476, 477, 478, and 479, there are authorized to be appropriated $12,000,000 for fiscal year 1986, $13,000,000 for fiscal year 1987, and $14,000,000 for fiscal year 1988. Funds appropriated under this section shall remain available for such purposes until the end of the fiscal year immediately following the fiscal year for which they were appropriated.

DEFINITIONS

SEC. 473. As used in this subpart—

(1) the term "medical library" means a library related to the sciences related to health; and

(2) the term "sciences related to health" includes medicine, osteopathy, dentistry, and public health, and fundamental and applied sciences when related thereto.

NATIONAL MEDICAL LIBRARIES ASSISTANCE ADVISORY BOARD

SEC. 474. (a) The Board of Regents of the National Library of Medicine shall also serve as the National Medical Libraries Assistance Advisory Board (hereafter in this subpart referred to as the "Board").

(b) The Board shall advise and assist the Secretary in the preparation of general regulations and with respect to policy matters arising in the administration of this subpart.

(c) The Secretary may use the services of any member of the Board, in connection with matters related to the administration of this part for such periods, in addition to conference periods, as the Secretary may determine.

(d) Appointed members of the Board who are not otherwise in the employ of the United States, while attending conferences of the Board or otherwise serving at the request of the Secretary in connection with the administration of this subpart, shall be entitled to receive compensation, per diem in lieu of subsistence, and travel expenses in the same manner and under the same conditions as that prescribed under section 208(c) when attending conferences, traveling, or serving at the request of the Secretary in connection with the Board's function under this section.

GRANTS FOR TRAINING IN MEDICAL LIBRARY SCIENCES

SEC. 475. The Secretary shall make grants—

(1) to individuals to enable them to accept traineeships and fellowships leading to postbaccalaureate academic degrees in the field of medical library science, in related fields pertaining to sciences related to health, or in the field of the communication of information;

(2) to individuals who are librarians or specialists in information on sciences relating to health, to enable them to undergo intensive training or retraining so as to attain greater competence in their occupations (including competence in the fields of automatic data processing and retrieval);

(3) to assist appropriate public and private nonprofit institutions in developing, expanding, and improving training programs in library science and the field of communications of information pertaining to sciences relating to health; and

(4) to assist in the establishment of internship programs in established medical libraries meeting standards which the Secretary shall prescribe.

ASSISTANCE FOR SPECIAL SCIENTIFIC PROJECTS, AND FOR RESEARCH AND DEVELOPMENT IN MEDICAL LIBRARY SCIENCE AND RELATED FIELDS

SEC. 476. (a) The Secretary shall make grants to physicians and other practitioners in the sciences related to health, to scientists, and to public or nonprofit private institutions on behalf of such physicians, other practitioners, and scientists for the compilation of existing, or the writing of original, contributions relating to scientific, social, or cultural advancements in sciences related to health. In making such grants, the Secretary shall make appropriate arrangements under which the facilities of the Library and the facilities of libraries of public and private nonprofit institutions of higher learning may be made available in connection with the projects for which such grants are made.

(b) The Secretary shall make grants to appropriate public or private nonprofit institutions and enter into contracts with appropriate

persons, for purposes of carrying out projects of research, investigations, and demonstrations in the field of medical library science and related activities and for the development of new techniques, systems, and equipment, for processing, storing, retrieving, and distributing information pertaining to sciences related to health.

GRANTS FOR ESTABLISHING, EXPANDING, AND IMPROVING THE BASIC RESOURCES OF MEDICAL LIBRARIES AND RELATED INSTRUMENTALITIES

SEC. 477. (a) The Secretary shall make grants of money, materials, or both, to public or private nonprofit medical libraries and related scientific communication instrumentalities for the purpose of establishing, expanding, and improving their basic medical library or related resources. A grant under this subsection may be used for—

(1) the acquisition of books, journals, photographs, motion picture and other films, and other similar materials;

(2) cataloging, binding, and other services and procedures for processing library resource materials for use by those who are served by the library or related instrumentality;

(3) the acquisition of duplication devices, facsimile equipment, film projectors, recording equipment, and other equipment to facilitate the use of the resources of the library or related instrumentality by those who are served by it; and

(4) the introduction of new technologies in medical librarianship.

(b)(1) The amount of any grant under this section to any medical library or related instrumentality shall be determined by the Secretary on the basis of the scope of library or related services provided by such library or instrumentality in relation to the population and purposes served by it. In making a determination of the scope of services served by any medical library or related instrumentality, the Secretary shall take into account—

(A) the number of graduate and undergraduate students making use of the resources of such library or instrumentality;

(B) the number of physicians and other practitioners in the sciences related to health utilizing the resources of such library or instrumentality;

(C) the type of supportive staffs, if any, available to such library or instrumentality;

(D) the type, size, and qualifications of the faculty of any school with which such library or instrumentality is affiliated;

(E) the staff of any hospital or hospitals or of any clinic or clinics with which such library or instrumentality is affiliated; and

(F) the geographic area served by such library or instrumentality and the availability within such area of medical library or related services provided by other libraries or related instrumentalities.

(2) Grants to medical libraries or related instrumentalities under this section shall be in such amounts as the Secretary may by regulation prescribe with a view to assuring adequate continuing financial support for such libraries or instrumentalities from other sources during and after the period for which grants are provided.

GRANTS AND CONTRACTS FOR ESTABLISHMENT OF REGIONAL MEDICAL LIBRARIES

SEC. 478. (a) The Secretary, with the advice of the Board, shall make grants to and enter into contracts with existing public or private nonprofit medical libraries so as to enable each of them to serve as the regional medical library for the geographical area in which it is located.

(b) The uses for which grants and contracts under this section may be employed include the—

(1) acquisition of books, journals, and other similar materials;

(2) cataloging, binding, and other procedures for processing library resource materials for use by those who are served by the library;

(3) acquisition of duplicating devices and other equipment to facilitate the use of the resources of the library by those who are served by it;

(4) acquisition of mechanisms and employment of personnel for the speedy transmission of materials from the regional library to local libraries in the geographic area served by the regional library; and

(5) planning for services and activities under this section.

(c)(1) Grants and contracts under this section shall only be made to or entered into with medical libraries which agree—

(A) to modify and increase their library resources, and to supplement the resources of cooperating libraries in the region, so as to be able to provide adequate supportive services to all libraries in the region as well as to individual users of library services; and

(B) to provide loan services to qualified users and make available photoduplicated or facsimile copies of biomedical materials which qualified requesters may retain.

(2) The Secretary, in awarding grants and contracts under this section, shall give priority to medical libraries having the greatest potential of fulfilling the needs for regional medical libraries. In determining the priority to be assigned to any medical library, the Secretary shall consider—

(A) the adequacy of the library (in terms of collections, personnel, equipment, and other facilities) as a basis for a regional medical library; and

(B) the size and nature of the population to be served in the region in which the library is located.

(d) Grants and contracts under this section for basic resource materials to a library may not exceed—

(1) 50 percent of the library's annual operating expense (exclusive of Federal financial assistance under this part) for the preceding year; or

(2) in case of the first year in which the library receives a grant under this section for basic resource materials, 50 percent of its average annual operating expenses over the past three years (or if it had been in operation for less than three years, its annual operating expenses determined by the Secretary in accordance with regulations).

FINANCIAL SUPPORT OF BIOMEDICAL SCIENTIFIC PUBLICATIONS

SEC. 479. (a) The Secretary, with the advice of the Board, shall make grants to, and enter into appropriate contracts with, public or private nonprofit institutions of higher education and individual scientists for the purpose of supporting biomedical scientific publications of a nonprofit nature and to procure the compilation, writing, editing, and publication of reviews, abstracts, indices, handbooks, bibliographies, and related matter pertaining to scientific works and scientific developments.

(b) Grants under this section in support of any single periodical publication may not be made for more than three years, except in those cases in which the Secretary determines that further support is necessary to carry out the purposes of this section.

GRANT PAYMENTS; RECORDS AND AUDIT

SEC. 480. (a) Payments under grants made under sections 475, 476, 477, 478, and 479 may be made in advance or by way of reimbursement and in such installments as the Secretary shall prescribe by regulation after consultation with the Board.

(b)(1) Each recipient of a grant under this subpart shall keep such records as the Secretary shall prescribe, including records which fully disclose the amount and disposition by such recipient of the proceeds of such grant, the total cost of the project or undertaking in connection with which such grant is given or used, and the amount of that portion of the cost of the project or undertaking supplied by other sources, and such other records as will facilitate an effective audit.

(2) The Secretary and the Comptroller General of the United States, or any of their duly authorized representatives, shall have access for the purpose of audit and examination to any books, documents, papers, and records of such recipients that are pertinent to any grant received under this subpart.

PART E—OTHER AGENCIES OF NIH

DIVISION OF RESEARCH RESOURCES

SEC. 482. The general purpose of the Division of Research Resources is to strengthen and enhance the research environments of entities engaged in health-related research by developing and supporting essential research resources.

JOHN E. FOGARTY INTERNATIONAL CENTER FOR ADVANCED STUDY IN THE HEALTH SCIENCES

SEC. 483. The general purpose of the John E. Fogarty International Center for Advanced Study in the Health Sciences is to—

(1) facilitate the assembly of scientists and others in the biomedical, behavioral, and related fields for discussion, study, and research relating to the development of health science internationally;

(2) provide research programs, conferences, and seminars to further international cooperation and collaboration in the life sciences;

(3) provide postdoctorate fellowships for research training in the United States and abroad and promote exchanges of senior scientists between the United States and other countries;

(4) coordinate the activities of the National Institutes of Health concerned with the health sciences internationally; and

(5) receive foreign visitors to the National Institutes of Health.

PART F—AWARDS AND TRAINING

NATIONAL RESEARCH SERVICE AWARDS

SEC. 485. (a)(1) The Secretary shall—

(A) provide National Research Service Awards for—

(i) biomedical and behavioral research at the National Institutes of Health and the Alcohol, Drug Abuse, and Mental Health Administration in matters relating to the cause, diagnosis, prevention, and treatment of the diseases or other health problems to which the activities of the National Institutes of Health and Administration are directed;

(ii) training at the National Institutes of Health and at the Administration of individuals to undertake such research;

(iii) biomedical and behavioral research and health services research (including research in primary medical care) at public and nonprofit private entities; and

(iv) pre-doctoral and post-doctoral training at public and private institutions of individuals to undertake biomedical and behavioral research; and

(B) make grants to public and nonprofit private institutions to enable such institutions to make National Research Service Awards for research (and training to undertake biomedical and behavioral research) in the matters described in subparagraph (A)(i) to individuals selected by such institutions.

A reference in this subsection to the National Institutes of Health or the Alcohol, Drug Abuse, and Mental Health Administration shall be considered to include the institutes, agencies, divisions, and bureaus included in the National Institutes of Health or under the Administration, as the case may be.

(2) National Research Service Awards may not be used to support residency training of physicians and other health professionals.

(3) In awarding National Research Service Awards under this section, the Secretary shall take account of the Nation's overall need for biomedical research personnel by giving special consideration to physicians who agree to undertake a minimum of two years of biomedical research.

(b)(1) No National Research Service Award may be made by the Secretary to any individual unless—

(A) the individual has submitted to the Secretary an application therefor and the Secretary has approved the application;

(B) the individual provides, in such form and manner as the Secretary shall by regulation prescribe, assurances satisfactory to the Secretary that the individual will meet the service requirement of subsection (c); and

(C) in the case of a National Research Service Award for a purpose described in subsection (a)(1)(A)(iii), the individual has been sponsored (in such manner as the Secretary may by regulation require) by the institution at which the research or training under the award will be conducted.

An application for an award shall be in such form, submitted in such manner, and contain such information, as the Secretary may by regulation prescribe.

(2) The making of grants under subsection (a)(1)(B) for National Research Service Awards shall be subject to review and approval by the appropriate advisory councils within the Department of Health and Human Services (A) whose activities relate to the research or training under the awards, or (B) for the entity at which such research or training will be conducted.

(3) No grant may be made under subsection (a)(1)(B) unless an application therefor has been submitted to and approved by the Secretary. Such application shall be in such form, submitted in such manner, and contain such information, as the Secretary may by regulation prescribe. Subject to the provisions of this section (other than paragraph (1)), National Research Service Awards made under a grant under subsection (a)(1)(B) shall be made in accordance with such regulations as the Secretary shall prescribe.

(4) The period of any National Research Service Award made to any individual under subsection (a) may not exceed—

(A) five years in the aggregate for predoctoral training; and

(B) three years in the aggregate for postdoctoral training;

unless the Secretary for good cause shown waives the application of such limit to such individual.

(5) National Research Service Awards shall provide for such stipends, tuition, fees, and allowances (including travel and subsistence expenses and dependency allowances), adjusted periodically to reflect increases in the cost of living, for the recipients of the awards as the Secretary may deem necessary. A National Research Service Award made to an individual for research or research training at a non-Federal public or nonprofit private institution shall also provide for payments to be made to the institution for the cost of support services (including the cost of faculty salaries, supplies, equipment, general research support, and related items) provided such individual by such institution. The amount of any such payments to any institution shall be determined by the Secretary and shall bear a direct relationship to the reasonable costs of the institution for establishing and maintaining the quality of its biomedical and behavioral research and training programs.

(c)(1) Each individual who is awarded a National Research Service Award (other than an individual who is a pre-baccalaureate student who is awarded a National Research Service Award for research training) shall, in accordance with paragraph (3), engage in health research or teaching or any combination thereof which is in accordance with the usual patterns of academic employment, for a period computed in accordance with paragraph (2).

(2) For each month for which an individual receives a National Research Service Award which is made for a period in excess of twelve months, such individual shall engage in one month of health

research or teaching or any combination thereof which is in accordance with the usual patterns of academic employment.

(3) The requirement of paragraph (1) shall be complied with by any individual to whom it applies within such reasonable period of time, after the completion of such individual's award, as the Secretary shall by regulation prescribe. The Secretary shall by regulation prescribe the type of research and teaching in which an individual may engage to comply with such requirement and such other requirements respecting research and teaching as the Secretary considers appropriate.

(4)(A) If any individual to whom the requirement of paragraph (1) is applicable fails, within the period prescribed by paragraph (3), to comply with such requirements, the United States shall be entitled to recover from such individual an amount determined in accordance with the formula—

$$A = \phi \frac{t - s}{t}$$

in which "A" is the amount the United States is entitled to recover; "ϕ" is the sum of the total amount paid under one or more National Research Service Awards to such individual; "t" is the total number of months in such individual's service obligation; and "s" is the number of months of such obligation served by such individual in accordance with paragraphs (1) and (2) of this subsection.

(B) Any amount which the United States is entitled to recover under subparagraph (A) shall, within the three-year period beginning on the date the United States becomes entitled to recover such amount, be paid to the United States. Until any amount due the United States under subparagraph (A) on account of any National Research Service Award is paid, there shall accrue to the United States interest on such amount at a rate fixed by the Secretary of the Treasury after taking into consideration private consumer rates of interest prevailing on the date the United States becomes entitled to such amount.

(5)(A) Any obligation of an individual under paragraph (1) shall be canceled upon the death of such individual.

(B) The Secretary shall by regulation provide for the waiver or suspension of any such obligation applicable to any individual whenever compliance by such individual is impossible or would involve substantial hardship to such individual or would be against equity and good conscience.

(d) There are authorized to be appropriated to make payments under National Research Service Awards and under grants for such awards $223,000,000 for fiscal year 1986, $235,000,000 for fiscal year 1987, and $245,000,000 for fiscal year 1988. Of the amounts appropriated under this subsection—

(1) not less than 15 percent shall be made available for payments under National Research Service Awards provided by the Secretary under subsection (a)(1)(A);

(2) not less than 50 percent shall be made available for grants under subsection (a)(1)(B) for National Research Service Awards;

(3) one-half of one percent shall be made available for payments under National Research Service Awards which (A) are made to individuals affiliated with entities which have received grants or contracts under section 780, 784, or 786, and (B) are for research in primary medical care; and one-half of one percent shall be made available for payments under National Research Service Awards made for health services research by the National Center for Health Services Research and Health Care Technology Assessment under section 304(a)(3); and

(4) not more than 4 percent may be obligated for National Research Service Awards for periods of three months or less.

VISITING SCIENTIST AWARDS

SEC. 486. (a) The Secretary may make awards (hereafter in this section referred to as "Visiting Scientist Awards") to outstanding scientists who agree to serve as visiting scientists at institutions of postsecondary education which have significant enrollments of disadvantaged students. Visiting Scientist Awards shall be made by the Secretary to enable the faculty and students of such institutions to draw upon the special talents of scientists from other institutions for the purpose of receiving guidance, advice, and instruction with regard to research, teaching, and curriculum development in the biomedical and behavioral sciences and such other aspects of these sciences as the Secretary shall deem appropriate.

(b) The amount of each Visiting Scientist Award shall include such sum as shall be commensurate with the salary or remuneration which the individual receiving the award would have been entitled to receive from the institution with which the individual has, or had, a permanent or immediately prior affiliation. Eligibility for and terms of Visiting Scientist Awards shall be determined in accordance with regulations the Secretary shall prescribe.

STUDIES RESPECTING BIOMEDICAL AND BEHAVIORAL RESEARCH PERSONNEL

SEC. 487. (a) Within five years after the date of enactment of the Health Research Extension Act of 1985, and every five years thereafter, the Secretary shall, in accordance with subsection (b), arrange for the conduct of a study to—

(1) establish (A) the Nation's overall need for biomedical and behavioral research personnel, (B) the subject areas in which such personnel are needed and the number of such personnel needed in each such area, and (C) the kinds and extent of training which should be provided such personnel;

(2) assess (A) current training programs available for the training of biomedical and behavioral research personnel which are conducted under this Act, at or through national research institutes under the National Institutes of Health and insti-

tutes under the Alcohol, Drug Abuse, and Mental Health Administration, and (B) other current training programs available for the training of such personnel;

(3) identify the kinds of research positions available to and held by individuals completing such programs;

(4) determine, to the extent feasible, whether the programs referred to in clause (B) of paragraph (2) would be adequate to meet the needs established under paragraph (1) if the programs referred to in clause (A) of paragraph (2) were terminated; and

(5) determine what modifications in the programs referred to in paragraph (2) are required to meet the needs established under paragraph (1).

(b)(1) The Secretary shall request the National Academy of Sciences to conduct each study required by subsection (a) under an arrangement under which the actual expenses incurred by such Academy in conducting each such study will be paid by the Secretary. If the National Academy of Sciences is willing to do so, the Secretary shall enter into such an arrangement with such Academy for the conduct of each such study.

(2) If the National Academy of Sciences is unwilling to conduct any such study under such an arrangement, then the Secretary shall enter into a similar arrangement with other appropriate nonprofit private groups or associations under which such groups or associations will conduct such study and prepare and submit the reports thereon as provided in subsection (c).

(3) The National Academy of Sciences or other group or association conducting each study required by subsection (a) shall conduct each such study in consultation with the Director of NIH.

(c) A report on the results of each study required under subsection (a) shall be submitted by the Secretary to the Committee on Energy and Commerce of the House of Representatives and the Committee on Labor and Human Resources of the Senate.

PART G—GENERAL PROVISIONS

INSTITUTIONAL REVIEW BOARDS; ETHICS GUIDANCE PROGRAM

SEC. 489. (a) The Secretary shall by regulation require that each entity which applies for a grant, contract, or cooperative agreement under this Act for any project or program which involves the conduct of biomedical or behavioral research involving human subjects submit in or with its application for such grant, contract, or cooperative agreement assurances satisfactory to the Secretary that it has established (in accordance with regulations which the Secretary shall prescribe) a board (to be known as an "Institutional Review Board") to review biomedical and behavioral research involving human subjects conducted at or supported by such entity in order to protect the rights of the human subjects of such research.

(b)(1) The Secretary shall establish a program within the Department of Health and Human Services under which requests for clarification and guidance with respect to ethical issues raised in connection with biomedical or behavioral research involving human subjects are responded to promptly and appropriately.

(2) The Secretary shall establish a process for the prompt and appropriate response to information provided to the Director of NIH

respecting incidences of violations of the rights of human subjects of research for which funds have been made available under this Act. The process shall include procedures for the receiving of reports of such information from recipients of funds under this Act and taking appropriate action with respect to such violations.

PEER REVIEW REQUIREMENTS

SEC. 490. (a)(1) The Secretary, acting through the Director of NIH, shall by regulation require appropriate technical and scientific peer review of—

(A) grants and cooperative agreements under this Act for biomedical and behavioral research; and

(B) biomedical and behavioral research and development contracts to be administered through the National Institutes of Health.

(2) Regulations promulgated under paragraph (1) shall require that the review of grants, contracts, and cooperative agreements required by the regulations be conducted—

(A) in a manner consistent with the system for scientific peer review applicable on the date of the effective date of the Health Research Extension Act of 1985 to grants under this Act for biomedical and behavioral research;

(B) to the extent practical, by peer review groups performing such review on or before such date; and

(C) in accordance with section 405(c)(3).

(b) The Director of NIH shall establish procedures for periodic, technical, and scientific peer review of research at the National Institutes of Health. Such procedures shall require that—

(1) the reviewing entity be provided a written description of the research to be reviewed; and

(2) the reviewing entity provide the advisory council of the national research institute involved with such description and the results of the review by the entity.

PROTECTION AGAINST SCIENTIFIC FRAUD

SEC. 491. (a) The Secretary shall by regulation require that each entity which applies for a grant, contract, or cooperative agreement under this Act for any project or program which involves the conduct of biomedical or behavioral research submit in or with its application for such grant, contract, or cooperative agreement assurances satisfactory to the Secretary that such entity—

(1) has established (in accordance with regulations which the Secretary shall prescribe) an administrative process to review reports of scientific fraud in connection with biomedical and behavioral research conducted at or sponsored by such entity; and

(2) will report to the Secretary any investigation of alleged scientific fraud which appears substantial.

(b) The Director of NIH shall establish a process for the prompt and appropriate response to information provided the Director of NIH respecting scientific fraud in connection with projects for which funds have been made available under this Act. The process shall include procedures for the receiving of reports of such infor-

mation from recipients of funds under this Act and taking appropriate action with respect to such fraud.

RESEARCH ON PUBLIC HEALTH EMERGENCIES

SEC. 492. (a) If the Secretary determines, after consultation with the Director of NIH, the Commissioner of the Food and Drug Administration, or the Director of the Centers for Disease Control, that a disease or disorder constitutes a public health emergency, the Secretary, acting through the Director of NIH—

(1) shall expedite the review by advisory councils under section 406 and the peer review required by regulations under section 490 of grants for research on such disease or disorder or proposals for contracts for such research;

(2) shall exercise the authority in section 3709 of the Revised Statutes (41 U.S.C. 5) respecting public exigencies to waive the advertising requirements of such section in the case of proposals for contracts for such research;

(3) may provide administrative supplemental increases in existing grants and contracts to support new research relevant to such disease or disorder; and

(4) shall disseminate, to health professionals and the public, information on the cause, prevention, and treatment of such disease or disorder that has been developed in research assisted under this section.

The amount of an increase in a grant or contract provided under paragraph (3) may not exceed one-half the original amount of the grant or contract.

(b) Not later than 90 days after the end of a fiscal year, the Secretary shall report to the Committee on Energy and Commerce of the House of Representatives and the Committee on Labor and Human Resources of the Senate on actions taken under subsection (a) in such fiscal year.

ANIMALS IN RESEARCH

SEC. 493. (a) The Secretary, acting through the Director of NIH, shall establish guidelines for the following:

(1) The proper care of animals to be used in biomedical and behavioral research.

(2) The proper treatment of animals while being used in such research. Guidelines under this paragraph shall specify—

(A) the appropriate use of tranquilizers, analgesics, anesthetics, paralytics, and euthanasia for animals in such research; and

(B) appropriate pre-surgical and post-surgical veterinary medical and nursing care for animals in such research.

Such guidelines shall not be construed to prescribe methods of research.

(3) The organization and operation of animal care committees in accordance with subsection (b).

(b)(1) Guidelines of the Secretary under subsection (a)(3) shall require animal care committees at each entity which conducts biomedical and behavioral research with funds provided under this Act (including the National Institutes of Health and the national re-

search institutes) to assure compliance with the guidelines established under subsection (a).

(2) Each animal care committee shall be appointed by the chief executive officer of the entity for which the committee is established, shall be composed of not fewer than three members, and shall include at least one individual who has no association with such entity and at least one doctor of veterinary medicine.

(3) Each animal care committee of a research entity shall—

(A) review the care and treatment of animals in all animal study areas and facilities of the research entity at least semiannually to evaluate compliance with applicable guidelines established under subsection (a) for appropriate animal care and treatment;

(B) keep appropriate records of reviews conducted under subparagraph (A); and

(C) for each review conducted under subparagraph (A), file with the Director of NIH at least annually (i) a certification that the review has been conducted, and (ii) reports of any violations of guidelines established under subsection (a) or assurances required under paragraph (1) which were observed in such review and which have continued after notice by the committee to the research entity involved of the violations.

Reports filed under subparagraph (C) shall include any minority views filed by members of the committee.

(c) The Director of NIH shall require each applicant for a grant, contract, or cooperative agreement involving research on animals which is administered by the National Institutes of Health or any national research institute to include in any application or contract proposal submitted after the expiration of the twelve-month period beginning on the effective date of this section—

(1) assurances satisfactory to the Director of NIH that—

(A) the applicant meets the requirements of the guidelines established under paragraphs (1) and (2) of subsection (a) and has an animal care committee which meets the requirements of subsection (b); and

(B) scientists, animal technicians, and other personnel involved with animal care, treatment, and use by the applicant have available to them instruction or training in the humane practice of animal maintenance and experimentation, and the concept, availability, and use of research or testing methods that limit the use of animals or limit animal distress; and

(2) a statement of the reasons for the use of animals in the research to be conducted with funds provided under such grant or contract.

Notwithstanding subsection (a)(2) of section 553 of title 5, United States Code, regulations under this subsection shall be promulgated in accordance with the notice and comment requirements of such section.

(d) If the Director of NIH determines that—

(1) the conditions of animal care, treatment, or use in an entity which is receiving a grant, contract, or cooperative agreement involving research on animals under this title do not meet applicable guidelines established under subsection (a);

(2) the entity has been notified by the Director of NIH of such determination and has been given a reasonable opportunity to take corrective action; and

(3) no action has been taken by the entity to correct such conditions;

the Director of NIH shall suspend or revoke such grant or contract under such conditions as the Director determines appropriate.

(e) No guideline or regulation promulgated under subsection (a) or (c) may require a research entity to publicly disclose trade secrets or commercial or financial information which is privileged or confidential.

USE OF APPROPRIATIONS UNDER THIS TITLE

SEC. 494. Appropriations to carry out the purposes of this title shall be available for the acquisition of land or the erection of buildings only if so specified. Such appropriations, unless otherwise expressly provided, may be expended in the District of Columbia for—

(1) personal services;

(2) stenographic recording and translating services;

(3) travel expenses (including the expenses of attendance at meetings when specifically authorized by the Secretary);

(4) rental;

(5) supplies and equipment;

(6) purchase and exchange of medical books, books of reference, directories, periodicals, newspapers, and press clippings;

(7) purchase, operation, and maintenance of passenger motor vehicles;

(8) printing and binding (in addition to that otherwise provided by law); and

(9) all other necessary expenses in carrying out this title.

Such appropriations may be expended by contract if deemed necessary, without regard to section 3709 of the Revised Statutes (41 U.S.C. 5).

GIFTS

SEC. 495. The Secretary may, in accordance with section 2101, accept conditional gifts for the National Institutes of Health or a national research institute or for the acquisition of grounds or for the erection, equipment, or maintenance of facilities for the National Institutes of Health or a national research institute. Donations equal to or in excess of $50,000 for the National Institutes of Health or a national research institute for carrying out the purposes of this title may be acknowledged by the establishment within the National Institutes of Health or national research institute of suitable memorials to the donors.

FETAL RESEARCH

SEC. 496. (a) The Secretary may not conduct or support any research or experimentation, in the United States or in any other country, on a nonviable living human fetus ex utero or a living human fetus ex utero for whom viability has not been ascertained unless the research or experimentation—

(1) may enhance the well-being or meet the health needs of the fetus or enhance the probability of its survival to viability; or

(2) will pose no added risk of suffering, injury, or death to the fetus and the purpose of the research or experimentation is the development of important biomedical knowledge which cannot be obtained by other means.

(b) In administering the regulations for the protection of human research subjects which—

(1) apply to research conducted or supported by the Secretary;

(2) involve living human fetuses in utero; and

(3) are published in section 46.208 of part 46 of title 45 of the Code of Federal Regulations;

or any successor to such regulations, the Secretary shall require that the risk standard (published in section 46.102(g) of such part 46 or any successor to such regulations) be the same for fetuses which are intended to be aborted and fetuses which are intended to be carried to term.

(c)(1) The Biomedical Ethics Advisory Committee appointed under section 381 shall conduct a study of the nature, advisability, and biomedical and ethical implications of exercising any waiver of the risk standard published in section 46.102(g) of such part 46 (or any successor to such regulations). The Committee shall complete the study and report its findings to the Biomedical Ethics Board established under section 381 not later than the expiration of thirty months after the effective date of this section. The report shall include the recommendations, if any, of the Committee on the advisability of the authority for such a waiver and the circumstances under which such a waiver might be granted. The Biomedical Ethics Board shall transmit the report to the Secretary, the Committee on Energy and Commerce of the House of Representatives, and the Committee on Labor and Human Resources of the Senate.

(2) During the thirty-six-month period beginning on the effective date of this section, the Secretary may not grant (under section 46.211 of part 45 of title 46 of the Code of Federal Regulations or any successor to such section) a modification or waiver for fetal research.

(3) Effective October 31, 1988, paragraph (2) is repealed.

CONSTRUCTION OF TITLE

SEC. 497. This title shall not be construed as limiting (1) the functions or authority of the Secretary under section 301 or of any officer or agency of the United States, relating to the study, prevention, diagnosis, and treatment of any disease for which a separate national research institute is established under this title, or (2) the expenditure of any funds therefor.

TITLE V—ADMINISTRATION AND COORDINATION OF THE NATIONAL INSTITUTE OF MENTAL HEALTH, THE NATIONAL INSTITUTE ON ALCOHOL ABUSE AND ALCOHOLISM, AND THE NATIONAL INSTITUTE ON DRUG ABUSE

PART A—ADMINISTRATION AND INSTITUTES

ALCOHOL, DRUG ABUSE, AND MENTAL HEALTH ADMINISTRATION

SEC. 501. * * *

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PEER REVIEW

SEC. 606. (a) * * *

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(e)(1) If the direct cost of a grant or contract (described in subsection (a)) to be made does not exceed $50,000, the Secretary may make such grant or cooperative agreement only if such grant or cooperative agreement is recommended after peer review required by regulations under subsections (a) and (b).

(2) If the direct cost of a grant or contract (described in subsection (a)) to be made equals or exceeds $50,000, the Secretary may make such grant or cooperative agreement only if such grant or cooperative agreement is recommended after peer review by regulations under subsections (a) and (b), and is recommended by the National Advisory Mental Health Council, the National Advisory Council on Alcohol Abuse and Alcoholism, or the National Advisory Council on Drug Abuse, as is appropriate.

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TITLE XI—GENETIC DISEASES, HEMOPHILIA PROGRAMS, AND SUDDEN INFANT DEATH SYNDROME

PART A—GENETIC DISEASES

RESEARCH PROJECT GRANTS AND CONTRACTS

SEC. 1102. * * *

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PART B—SUDDEN INFANT DEATH SYNDROME

SUDDEN INFANT DEATH SYNDROME RESEARCH AND RESEARCH REPORTS

SEC. 1122. (a) From the sums appropriated to the National Institute of Child Health and Human Development [under section 441], the Secretary shall assure that there are applied to research of the type described in subparagraphs (A) and (B) of subsection (b)(1) of this section such amounts each year as will be adequate, given the leads and findings then available from such research, in order to make maximum feasible progress toward identification of

infants at risk of sudden death syndrome and prevention of sudden infant death syndrome.

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Other Law Affected by This Act

ORPHAN DRUG ACT

(Public Law 97–414)

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TECHNICAL AMENDMENTS TO THE PUBLIC HEALTH SERVICE ACT

SEC. 8. (a) * * *

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[(w) From the funds appropriated under section 414B of such Act or under any other applicable provision of law, the Secretary of Health and Human Services shall provide for the development and support of not less than ten comprehensive centers for sickle cell disease.]

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